Medtronic

5392

Dual Chamber Temporary External Pacemaker

Technical Manual

! USA

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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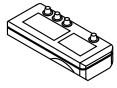
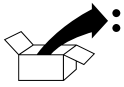
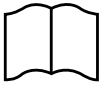
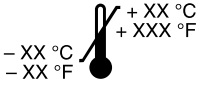
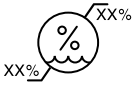
1 Overview

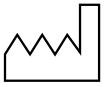
1.1 About this manual

This manual describes the features and functions of the Medtronic Model 5392 Dual Chamber Temporary External Pacemaker (referred to as the “temporary pacemaker”).

1.2 Symbols

Explanation of symbols	
	System meets the applicable Canadian and U.S. electrical safety standards.
	Consult instructions for use
	Caution
	Conformité Européenne (European Conformity) This symbol means that the device fully complies with European Directive 93/42/EEC.
	Temporary external pacemaker
A	Atrium chamber designator
V	Ventricle chamber designator
	For atrial use
	For ventricular use

Explanation of symbols	
	Defibrillation-proof type CF applied part
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.Medtronic.com for instructions on proper disposal of this product.
	For US audiences only
	Package contents
	Dual chamber temporary pacemaker
	Product documentation
	Accessories
	Storage temperature limitation
	Humidity limitation
	Battery
	Reorder number
	Authorized representative in the European Community
	Manufacturer/Date of manufacture

Explanation of symbols	
	Date of manufacture
	Serial number
	Non-ionizing electromagnetic radiation
	Notice of proper disposal
	This product conforms to IP21. There are no openings that allow the user to insert a finger or similarly sized objects. The product is resistant to dripping water or vertically falling drops.
	China RoHS
	MR Unsafe. An item that is known to pose hazards in all MR environments.

1.3 General description

The temporary pacemaker is a battery-powered, dual chamber, temporary pacemaker designed primarily for temporary antibradycardia pacing therapy. The temporary pacemaker provides 7 selectable modes of pacing therapy: DDD, DDI, DOO, AAI, AOO, VVI, and VOO. High-rate, burst pacing therapy up to 800 ppm for atrial tachyarrhythmias is available in the asynchronous mode.[1]

The temporary pacemaker typically is connected to temporary transvenous, epicardial, or myocardial pacing leads in a bipolar configuration, using either Medtronic patient cables, Medtronic surgical cables, or compatible patient cables (see Section 1.6).

The temporary pacemaker operates using 2 LR6-sized (AA-sized) alkaline batteries (see Section 7.1). The batteries are installed in the battery drawer at the bottom of the temporary pacemaker.

[1] For atrial use only.

Note: The temporary pacemaker is a constant current device. When it emits a pulse, the current output is maintained at a constant value. This value is set by the output control and does not vary.

1.3.1 Safety features

The temporary pacemaker includes the following safety features:

- Self-test function
- Low battery indicator
- Lock feature to prevent accidental change of parameters
- Safe, two-step operation to turn off the temporary pacemaker to avoid unintended shutdown
- Runaway rate protection
- Protection from defibrillation shock
- Continuous operation during battery replacement (see Section 7.1)
- Electrostatic protection
- Minimized susceptibility to electromagnetic and magnetic interference

1.3.2 Operating features

The temporary pacemaker includes the following operating features:

- Single chamber pacing modes – AAI, AOO, VVI, and VOO
- Dual chamber pacing modes – DDD, DDI, DOO
- No pacing therapy – OOO
- Easy-to-view rate and output settings
- Pacing and sensing status indicators – shows temporary pacemaker interaction with the heart
- Low battery indicator – indicates when to replace the batteries
- Four-dial operation – provides therapy for most pacing needs
- Rate-dependent parameters – rate adjustment automatically sets Upper Rate, PVARP, and A-V Interval
- Lock/Unlock key – safeguards against unintentional parameter changes
- Lower screen messages – to aid in device operation

- Menu screens – for adjusting additional parameters, including sensitivity, rate-dependent parameters; for Rapid Atrial Pacing (RAP); for directly selecting 7 pacing modes (DDD, DDI, DOO, AAI, AOO, VVI, and VOO) or selecting no pacing therapy (OOO).
- Pause key – to suspend pacing and sensing to view the patient's intrinsic rhythm
- DOO/Emergency key – starts emergency dual chamber asynchronous (DOO) pacing at maximum atrial and ventricular outputs
- Automatic sensitivity adjustment
- Automatic mode switch during atrial arrhythmias

1.4 Intended use

The temporary pacemaker is used with a cardiac pacing lead system for temporary single or dual chamber pacing in a clinical environment by trained personnel. Train clinical personnel on the functionality and use of the temporary pacemaker prior to initial use of the device, as needed, and per clinic procedures. Contact your Medtronic representative to schedule training.

The temporary pacemaker can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic, or diagnostic purposes. The temporary pacemaker must be used in an environment where the patient is monitored continuously to ensure that it is operating properly and delivering appropriate therapy to the patient.

Specific indications for temporary cardiac pacing include, but are not limited to, the following:

- Complete heart block
- Sinus bradycardia
- Sick sinus syndrome
- Bradycardia with congestive heart failure
- Atrial and/or ventricular arrhythmias
- Cardiac arrest
- Support, management, and evaluation of a patient before permanent pacemaker implantation
- Support during permanent pacemaker replacement
- Cardiac complications during invasive or surgical procedures
- Support following cardiac surgery

- Acute myocardial infarction complicated by heart block
- Atrial tachyarrhythmias that require high-rate burst pacing for treatment

1.5 Package contents

The temporary pacemaker is supplied with the following items:

- Two LR6-sized (AA-sized) alkaline batteries (see Section 7.1)
- Literature

1.6 Compatible accessory components

The following compatible accessory components are available for the temporary pacemaker:

- Medtronic Model 5409 Disposable Pouch
- Medtronic Model 53922 Disposable Cover

The following reusable compatible cables are available for the temporary pacemaker:

- Medtronic Patient Cables (Model 5433 family)
- Medtronic Surgical Cables (Model 5832 family)

The following disposable compatible cables are available for the temporary pacemaker:

- Medtronic Surgical Cable (Model 5833 family)
- Medtronic Patient Cables (Model 5846 family)
- Medtronic Patient Cables (Model 5487 family)
- Compatible temporary transvenous, epicardial, or myocardial pacing leads

Contact your local Medtronic representative to order them.

1.7 Contraindications

There are no known contraindications for the use of temporary pacing as a means to control heart rate. However, the patient's age and medical condition may dictate the type of temporary pacemaker and lead system that the physician uses.

1.7.1 Atrial sensing

Pacing modes that allow sensing in the atrium to trigger a ventricular response are contraindicated in the presence of rapid atrial arrhythmias, such as atrial fibrillation or atrial flutter.

1.7.2 Atrial pacing

Atrial pacing is ineffective in the presence of atrial fibrillation or flutter.

Single chamber atrial pacing is contraindicated in the presence of AV conduction disorders.

1.7.3 Asynchronous pacing

Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms.

1.7.4 Atrial high-rate burst pacing therapy

Atrial high-rate burst pacing therapy is intended for use in the atrium only. High-rate burst pacing is contraindicated in the ventricle; it may result in life-threatening arrhythmias.

1.7.5 Concomitant pacing

Temporary pacing is contraindicated in the presence of another pacing system.

Do not use the temporary pacemaker to pace a patient while another pacing system is also actively pacing the patient. Concomitant pacing can occur where both pacing systems compete to pace the patient.

If concomitant pacing occurs, the temporary pacemaker may not be able to pace the patient, or may pace the patient asynchronously. Concomitant pacing could cause the temporary pacemaker to potentially pace into a T-Wave or result in a pacemaker-mediated tachycardia.

2 Warnings, precautions, and adverse events

2.1 Warnings

Patient monitoring – Monitor the patient continuously while the temporary pacemaker is in use to ensure it is operating properly and delivering appropriate therapy to the patient.

Equipment modification – Do not modify the temporary pacemaker. Modifications could impact the temporary pacemaker effectiveness and adversely affect patient safety.

Temporary pacemaker compatibility – Only connect items that have been specified as part of the temporary pacemaker or that have been specified as being compatible with the temporary pacemaker.

Temporary pacemaker use – The temporary pacemaker is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Defibrillation/cardioversion – The temporary pacemaker is protected from damage caused by internal defibrillation discharges up to 50 J (watt-seconds) and external defibrillation discharges up to 360 J. However, it is recommended that paddles be placed as far away from the temporary pacemaker or the lead system as is practical.

Whenever possible, for the safety of the patient, disconnect the temporary pacemaker from the implanted lead system before defibrillating or cardioverting. Excessive defibrillation energy can damage the temporary pacemaker. This can result in a large current flowing through the implanted lead system and temporary pacemaker, which could reduce intended defibrillation energy delivered to the patient or cause myocardial damage.

If damage to the temporary pacemaker is suspected due to defibrillation, disconnect it from the patient and return it to Medtronic for service.

Line-powered equipment – An implanted lead or a lead with an extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of tachyarrhythmias resulting from alternating current leakage, extreme caution must be taken to properly ground all line-powered equipment used on or in the vicinity of the patient.

Electrosurgical units (cautery) – Electrosurgical units can cause loss of pacing from oversensing or tachyarrhythmias by inducing current on the leads, and thus should never be used within 15 cm (6 in) of the pacemaker/lead system.

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction.

Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the temporary leads.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and leads.
- Continuously monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing.

Electromagnetic interference (EMI) – Pacemakers operating in the demand mode respond to intracardiac potentials with magnitudes of a few mV. This level of sensitivity makes the temporary pacemaker inherently sensitive to some external fields. In the presence of excessive levels of interference, the temporary pacemaker may inhibit completely or revert to asynchronous operation, pacing at the rate set by the RATE dial.

It is recommended that the temporary pacemaker be set to an asynchronous pacing mode at a rate higher than the patient's intrinsic rate when operated in the presence of strong electromagnetic interference (EMI).

Sources of excessively strong EMI that may temporarily affect the operation of the temporary pacemaker include the following:

- Electrosurgical equipment
- Diathermy equipment
- Some medical telemetry equipment (when operated within 1 m [about 3 feet] of the pacemaker)
- Communication transmitters such as cellular phones, "walkie talkies", and transmitters in emergency transport vehicles
- Magnetic resonance imaging (MRI) equipment

Atrial High-Rate Burst Pacing Therapy (Rapid Atrial Pacing) – Use of high rates in the atrium could result in high-rate conduction to the ventricle. Defibrillation equipment should be on standby, immediately available during atrial high-rate burst pacing therapy.

There is no ventricular back-up pacing during delivery of atrial high-rate burst pacing therapy.

Connecting the lead system – The patient cables should be connected to the temporary pacemaker before the lead(s) is connected to the patient cable(s).

Handling implanted leads – When handling implanted leads (temporary or permanent), the terminal pins or exposed metal must not be touched nor be allowed to contact electrically conductive or wet surfaces.

MR unsafe – The temporary pacemaker is MR unsafe. Do not bring the temporary pacemaker into Zone 4 (magnet room), as defined by the American College of Radiology.

2.2 Precautions

Random failures – The physician should be aware that operational failure of the temporary pacemaker can occur as the result of battery depletion, mishandling, or random component failure.

Possible operational failures of the temporary pacemaker can include the following:

- No output or erratic output
- No sensing or erratic sensing
- False indicator light signals
- Inappropriate variance of rate, output pulse width, or output amplitude
- Reversion to asynchronous pacing
- Loss of control of rate, output, sensitivity, or power

If loss of control of rate, output, sensitivity, or power occurs, and it is not due to a low battery, disconnect the temporary pacemaker from the patient and return it to Medtronic for service.

Temporary pacemaker repair – Do not attempt to repair the temporary pacemaker. Only a qualified Medtronic Technical Services representative can repair the temporary pacemaker. Contact Medtronic at the telephone number on the back cover of this manual if the temporary pacemaker requires service.

Service condition – Before each use, evaluate the temporary pacemaker for damage and observable defects. Do not use the temporary pacemaker if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken. If the temporary pacemaker has any observable defects, contact Medtronic at the telephone number on the back cover of this manual for service.

Cleaning, disinfection, and sterilization – Clean and disinfect the temporary pacemaker before each use for a new patient. Clean and sterilize the reusable cables before each use for a new patient.

Batteries – Only install the recommended batteries in the temporary pacemaker. Batteries with different physical dimensions, non-alkaline (e.g., lithium or rechargeable) or batteries

with contamination on the battery terminals, may result in erratic operation of the temporary pacemaker, no pacing output, or damage to the temporary pacemaker, specifically to the battery compartment.

Replace the batteries for each new patient and when the low battery indicator flashes during temporary pacemaker operation.

Only use new, fresh batteries that have not passed their expiration date.

Inspect battery terminals for contamination. Using batteries with contaminated terminals can result in the temporary pacemaker turning off, decreased battery life, or corrosion to the battery compartment.

Check the battery status at least twice daily. Replace alkaline batteries at least once every week when the temporary pacemaker is in continuous use or when the low battery indicator flashes. Verify that the battery drawer is fully closed and latched in place.

Failure to ensure that the battery drawer is fully latched may result in loss of power. Continued temporary pacemaker operation is not an indication that the battery drawer is properly latched.

Battery installation – Ensure that the new, fresh batteries are installed with the correct battery polarity by verifying that the batteries align with the polarity markings on the inside of the battery drawer. The temporary pacemaker requires proper battery polarity for operation. After installing the batteries, ensure that the battery status indicator displays full battery power and that the low battery indicator is not flashing. The temporary pacemaker may temporarily continue to pace and sense with weak, dead, or incorrectly installed batteries.

Pacing leads and cables – Improper connection, displacement, or fracture of leads or cables may result in pacemaker system failure. Inspect leads and cables for damage before each use.

Pacing system adjustments – Monitor the patient's ECG and blood pressure. Keep defibrillation equipment on standby, immediately available for emergency use during evaluation of stimulation and sensing thresholds, pacemaker and pacing lead connections and adjustments, and atrial high-rate burst pacing therapy.

Default DDD pacing mode – The default power-up settings for the DDD pacing mode are not always appropriate for every patient or situation. Select the appropriate pacing mode to meet the pacing needs of the patient.

Patient monitoring after defibrillation – Monitor the patient after a defibrillation has occurred to verify that the temporary pacemaker and the cable/lead systems are still delivering the appropriate therapy.

Bipolar lead systems – Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference. Separation between the positive (+) electrode and negative (–) electrode of the same lead system should not exceed 15 mm (0.6 in). Place the atrial and ventricular lead systems at right angles to each other. Verify that the electrodes

of one system are a minimum of 4 cm (1.5 in) from the electrodes of the other system. Failure to follow these spacing recommendations could result in oversensing. Clinical risks for not following these spacing recommendations include, but are not limited to, loss of pacing output, asynchronous ventricular pacing, and pacemaker mediated tachycardia.

Unipolar lead systems – Unipolar lead systems are not recommended because they are more susceptible to electromagnetic interference, which may result in inappropriate pacing. Unipolar lead systems should not be used in the dual-chambered pacing modes because the current path of one lead system may interfere with the current path of the other.

Dual chamber pacing modes – Do not configure the temporary pacemaker in any of the dual chamber pacing modes unless both channels are connected to the heart. If the temporary pacemaker is configured in a dual chamber pacing mode and one of the channels is not connected, the open channel could pick up unintended noise. The noise can be interpreted as a sensed event and can lead to events such as, but not limited to, asynchronous ventricular pacing, unintended pacing inhibition, or ventricular tachycardia.

Avoid use of dual chamber pacing modes without an atrial connection as this could, in rare circumstances, result in inappropriate delivery of a ventricular pace on an intrinsic T-wave.

Atrial sensing – When programming to a mode that requires atrial sensing, the sensing threshold should be evaluated for sufficient safety margin.

Place the temporary pacing lead on the right atrial free wall, oriented along the direction of the myocardial fibers, approximately 1 cm (0.4 in) apart. It is important to achieve a sensing threshold of at least 1.0 mV. Set atrial sensitivity to a minimum of one-half the measured threshold. The setting ensures a minimum safety margin of two times the sensing threshold. Failure to follow this procedure can lead to delivery of asynchronous pulses.

Sensing thresholds – Do not use the temporary pacemaker to determine sensing thresholds for permanently implanted lead systems. When implanting a permanent pacemaker, Medtronic recommends the use of a pacing system analyzer (PSA).

Sensitivity settings – Since the sensitivity setting determines the smallest signal that can be sensed by the pacemaker, set the sensitivity dial to one-half the mV value of the patient's sensitivity threshold. This setting will provide a 2x safety margin to ensure proper sensing.

A more sensitive setting may be chosen to provide a greater safety margin. However, be aware that setting the sensitivity value too low (too sensitive) could result in inappropriate sensing of far field signals (for example, sensing of R-waves or T-waves on the atrial channel or P-waves on the ventricular channel), leading to inappropriate inhibition of pacing pulses.

Sensitivity threshold testing – Complete the sensitivity threshold testing to determine the appropriate settings for sensitivity. Clinical risks for failure to perform this step include, but are not limited to, asynchronous ventricular pacing and pacemaker mediated tachycardia.

Output threshold testing – Complete the output threshold testing to determine the appropriate settings for output. Clinical risks for failure to perform this step include, but are

not limited to, loss of capture, retrograde conduction, induced tachycardia, and loss of hemodynamic support.

High output and maximum sensitivity – Although the temporary pacemaker contains a safety pacing feature that prevents inappropriate inhibition of ventricular pacing due to far-field sensing, the simultaneous use of high output and maximum sensitivity (that is, the lowest mV value) in the presence of atrial flutter or fibrillation can result in fatal arrhythmias.

Electrostatic discharge (ESD) – The pacing lead(s) provides a low-impedance pathway to the heart. Therefore, it is recommended that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface before touching the patient, the cable, the leads, or the temporary pacemaker. Also, neutralize any static electricity from the patient by touching the patient away from (i.e., distal to) the leads.

Retrograde conduction – If retrograde P-waves are being sensed outside the rate-dependent, automatic Post-Ventricular-Atrial-Refractory Period (PVARP) setting, manually increase the PVARP until the retrograde waves fall inside the PVARP. Failure to follow this procedure may lead to a pacemaker-mediated tachycardia (PMT).

Termination of pacing – Abrupt termination of pacing stimuli may result in intervals of asystole before an intrinsic rhythm is re-established. Before terminating pacing, set the temporary pacemaker to a demand mode; then gradually reduce the pacing rate below the patient's intrinsic rate.

Pause key – Use the Pause key with care since the patient receives no pacing support (for a maximum of 10 s at a time) when the Pause key is pressed and held.

A-V Interval – Programming long A-V intervals may result in pacing the ventricle during the vulnerable period of ventricular repolarization, thus precipitating ventricular arrhythmias in unstable patients.

DOO/Emergency key – Use the DOO/Emergency key only when high-output asynchronous pacing (DOO) is needed. When the DOO/Emergency key is pressed, the emergency pacing mode is entered and remains in effect until the emergency pacing mode is deactivated. Press the Enter key to deactivate emergency pacing mode.

2.3 Environmental precautions

The temporary pacemaker has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. To avoid damage to the temporary pacemaker, observe the following precautions:

- Do not drop the temporary pacemaker or handle it in a way that might physically damage it. The temporary pacemaker may appear to work appropriately immediately after being dropped or mishandled, but operational damage may have occurred. Perform safety and technical checks if the temporary pacemaker has been dropped.
- Do not place the temporary pacemaker in any area where a patient may interact with it. Tampering with programmed parameters may have direct and serious patient health effects. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel (for example, patients or visitors). Medtronic recommends use of the Model 53922 Disposable Cover to reduce the risk of tampering with the programmed parameters.
- Avoid spilling fluid on the temporary pacemaker. The temporary pacemaker was carefully designed to minimize leakage, but fluid incursion may still occur. Medtronic recommends the use of a protective cover, such as the Model 5409 Disposable Pouch, to minimize fluid incursion.
- Avoid contaminating the patient cable receptacles with blood or other body fluids.
- Always use safe electrostatic discharge (ESD) procedures; the temporary pacemaker could be adversely affected by ESD.
- Do not open the temporary pacemaker. The seam joining the unit is designed to minimize fluid incursion and may not be effective if improperly opened and resealed. Furthermore, removing the label on the back of the temporary pacemaker may compromise the ESD barrier. Opening the temporary pacemaker voids the warranty.
- Do not sterilize the temporary pacemaker by gamma irradiation or steam (autoclave).
- Do not store the temporary pacemaker with the batteries in the battery drawer. Remove the batteries when the temporary pacemaker is not in use.
- Rapid temperature changes may affect proper operation. Always allow the temperature of the temporary pacemaker to stabilize in the environment in which it will be used before attachment and operation.
- Prolonged storage or operation of the temporary pacemaker in high humidity may affect proper operation. Allow the temporary pacemaker to completely dry after exposure to humidity.

Other environmental factors may impact proper performance of the temporary pacemaker in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the temporary pacemaker.

2.4 Adverse effects

Temporary pacemakers – Potential adverse effects related to the use of the temporary pacemaker include, but are not limited to the following:

- Asystole following abrupt cessation of pacing
- Inhibition or reversion in the presence of strong electromagnetic interference
- Initiation of a tachyarrhythmia or acceleration of an existing tachyarrhythmia

Atrial high-rate burst pacing – Atrial high-rate burst pacing may result in the onset of tachycardia, acceleration of an existing tachycardia, or fibrillation. Application of temporary atrial high-rate burst pacing should be performed in a carefully monitored and controlled patient environment. Monitor the patient's ECG and blood pressure. Keep defibrillation equipment on standby and immediately available for emergency use.

Dual chamber modes – In the DDI and DDD pacing modes, the ventricular sense amplifier may sense the atrial pacing pulse. Reducing the atrial amplitude, the ventricular sensitivity, and/or repositioning the electrodes may be necessary to avoid this situation.

Safety margins – Determine an adequate safety margin for sensing and pacing in both the ventricle and atrium. Failure to do so may result in inappropriate pacing.

Lead systems – Potential adverse effects related to the use of pacing lead systems used in conjunction with the temporary pacemaker include, but are not limited to the following:

- Inappropriate lead connections
- Inadvertent disconnection of the lead system
- Lead fracture or displacement causing intermittent or complete loss of capture and/or sensing
- Perforation and tamponade

Other potential adverse effects related to the use of any implanted lead system include, but are not limited to, the following:

- Myocardial irritability resulting in fibrillation
- Infarction
- Pericarditis
- Body rejection phenomena (local tissue reaction)
- Muscle and nerve stimulation
- Infection

Nerve or muscle stimulation can be caused by pacing lead contact with the nerve or muscle tissue and/or by high-output settings. The stimulation may be controlled by repositioning or replacing the electrode, or by reducing the output pulse amplitude.

3 Controls, indicators, and other features

3.1 Controls

The dials and keys used to control the functions and parameter settings of the temporary pacemaker are described in this chapter.

Note: All adjustments to the RATE, A (Atrial) OUTPUT, and V (Ventricular) OUTPUT dials take effect within the next two pacing cycles.

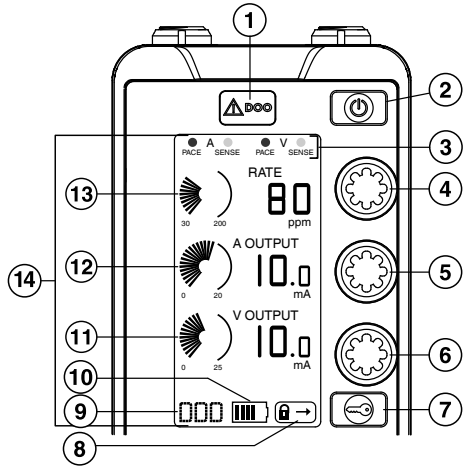
3.1.1 Temporary pacemaker controls and indicators

The upper screen indicators display the **RATE**, **A OUTPUT**, and **V OUTPUT** values, pacing and sensing status, the currently selected pacing mode, the battery status, and the lock indicator. See Figure 1.

The controls next to the upper screen are used for the following:

- To adjust the **RATE**, **A OUTPUT**, and **V OUTPUT** values using the RATE, A OUTPUT, and V OUTPUT dials
- To select high-output, dual-chamber asynchronous pacing (DOO for emergency) by pressing the DOO/Emergency key
- To turn on or turn off the temporary pacemaker by pressing the On/Off key

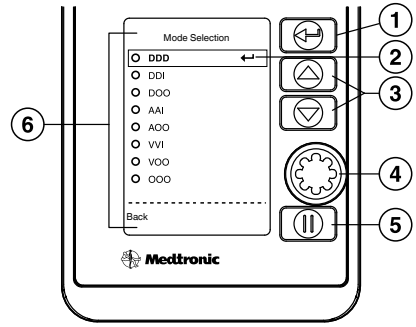
Figure 1. Controls and indicators for the upper screen



1 DOO/Emergency key
2 On/Off key
3 Pacing and sensing status bar indicators
4 RATE dial
5 A (Atrial) OUTPUT dial
6 V (Ventricular) OUTPUT dial
7 Lock/Unlock key
8 Lock indicator
9 Pacing mode indicator
10 Battery indicator
11 V (Ventricular) OUTPUT scale
12 A (Atrial) OUTPUT scale
13 RATE scale
14 Upper screen

The lower screen controls are used to select pacing modes, to adjust pacing parameter values, to deliver RAP pacing therapy, to resume synchronous pacing from asynchronous pacing, and to pause pacing therapy (see Figure 2). The lower screen displays the Mode Selection menu, pacing parameters, the RAP screens, and warnings and information messages.

Figure 2. Controls and indicators for the lower screen



1 Enter key
2 Selection indicator
3 Up/Down arrow keys
4 Menu Parameter dial
5 Pause key
6 Lower screen

Note: Upper and lower screens values contained in this manual are presented for reference only. Actual values may vary, depending on pacing mode, outputs, and parameter value selections.

3.1.2 DOO/Emergency key

Press the DOO/Emergency key to select high-output, dual-chamber asynchronous pacing (DOO for emergency) at any time, including when the temporary pacemaker is off or locked (see Figure 3). Avoid accidentally activating the DOO/Emergency key. See Section 7.1 for emergency pacing values.

Figure 3. DOO/Emergency key

3.1.3 On/Off key

Use the On/Off key to turn on or turn off the temporary pacemaker (see Figure 4).

Figure 4. On/Off key

3.1.4 Rate dial

Use the RATE dial to set the base rate, in ppm, at which pacing pulses are delivered (see Section 5.1.4).

3.1.5 A (Atrial) OUTPUT dial

The A (Atrial) OUTPUT dial is used to set the current amplitude, in mA, of the atrial pacing pulse (see Section 5.1.4).

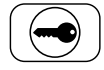
3.1.6 V (Ventricular) OUTPUT dial

The V (Ventricular) OUTPUT dial is used to set the current amplitude, in mA, of the ventricular pacing pulse (see Section 5.1.4).

3.1.7 Lock/Unlock key

The Lock/Unlock key locks the temporary pacemaker to prevent inadvertent adjustment of the pacing parameters, or unlocks the temporary pacemaker when it is locked. See Figure 5.

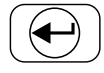
Figure 5. Lock/Unlock key



3.1.8 Enter key

The Enter key is used to select pacing modes in the Mode Selection menu, to select the Rapid Atrial Pacing (RAP) screen or the Mode Selection menu from the Pacing Parameters menu, to confirm power-off, to deliver Rapid Atrial Pacing (RAP) from the RAP menu, and to resume synchronous pacing from asynchronous pacing. See Figure 6.

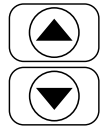
Figure 6. Enter key



3.1.9 Arrow keys

The Up and Down arrow keys are used to move the selection indicator in the lower screen. Press the Up or Down arrow keys to select pacing modes from the Mode Selection screen and to select pacing parameter values from a Pacing Parameters menu. See Figure 7.

Figure 7. Up and Down Arrow keys



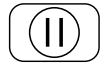
3.1.10 Menu parameter dial

The Menu Parameter dial is used to adjust the pacing parameters in the selected pacing mode (see Figure 2).

3.1.11 Pause key

Press and hold the Pause key to suspend pacing and sensing for up to 10 s (see Figure 8). When the Pause key is released or when the 10 s timer runs out, pacing and sensing resumes. Use the Pause key also to view the patient's intrinsic rhythm (see Section 5.1.3).

Figure 8. Pause key

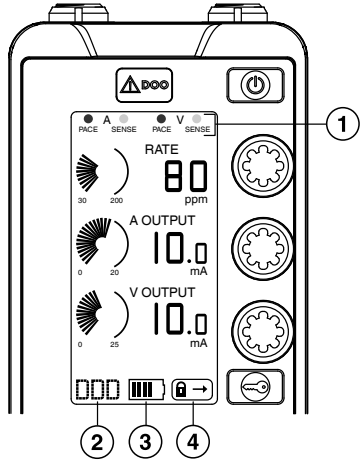


Caution: Use the Pause key with care. The patient receives no pacing support when the Pause key is pressed and held (for a maximum of 10 s at a time).

3.2 Indicators

The upper screen displays indicators for the pacing and sensing status bar, current pacing mode, battery power, and lock status. See Figure 9.

Figure 9. Indicators

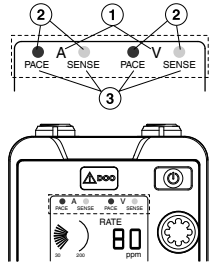


1 Pacing and sensing status bar indicators
2 Pacing mode indicator
3 Battery status indicator
4 Lock indicator

3.2.1 Pacing and sensing status bar indicators

The pacing and sensing status bar indicators, located at the top of the upper screen, identify which chambers the temporary pacemaker is currently set to pace and/or sense and indicate the current pacing mode (see Section 7.2). The indicators are the **A** (atrium) and **V** (ventricle) chamber indicators, the **PACE** and **SENSE** indicators, and the **PACE** and **SENSE** LEDs. See Figure 10.

Figure 10. Pacing and sensing status bar indicators



1 A and V chamber indicators
2 PACE and SENSE LEDs
3 PACE and SENSE indicators

The **A** and **V** chamber indicators, if present, indicate that the selected pacing mode enables the **A** and/or **V** chambers for pacing and sensing. However, pacing and sensing only occurs when the **PACE** and **SENSE** indicators are present.

The **PACE** and **SENSE** indicators, if present, indicate that the selected pacing mode enables pacing and sensing in the **A** and/or **V** chambers.

Note: While the **PACE** and **SENSE** indicators identify which chambers the temporary pacemaker is set to pace and/or sense, they do not indicate actual temporary pacemaker interaction with the heart.

The **PACE** and **SENSE** LEDs next to the **A** and **V** chamber indicators indicate delivery of a pacing pulse or a sensed event. The LEDs flash when the following pacing or sensing events occur, as follows:

- The green LED to the left of the **A** chamber indicator flashes each time the temporary pacemaker delivers a pacing pulse on the atrial channel.
- The green LED to the left of the **V** chamber indicator flashes each time the temporary pacemaker delivers a pacing pulse on the ventricular channel.

  Note: The green LED flashes indicate delivery of a pacing pulse, but they are not confirmation that the pacing pulse has initiated cardiac stimulation.

- The blue LED to the right of the **A** chamber indicator illuminates when events are sensed on the atrial channel. The **A SENSE** LED flashes when the temporary pacemaker detects events inside and outside the Atrial Refractory Period (ARP).
- The blue LED to the right of the **V** chamber indicator illuminates when events are sensed on the ventricular channel. The **V SENSE** LED flashes only when the temporary pacemaker detects an event outside a ventricular blanking period.

  Note: The blue LEDs indicate a sensed event by the temporary pacemaker, but they are not confirmation of a cardiac contraction.

3.2.2 Status indicators

The status indicators, at the bottom of the upper screen, display the pacing mode, battery status, and lock indicators.

3.2.2.1 Pacing mode indicator

The pacing mode indicator displays the current pacing mode.

3.2.2.2 Battery status indicator

The battery status indicator displays the amount of available battery power remaining. When all of the indicator bars are visible, the batteries have full power or have been replaced with a fresh set of batteries.

The low battery indicator, a red light, flashes behind the battery status indicator when only one bar is visible. When the low battery indicator begins flashing, the temporary pacemaker has approximately 24 hours or less of battery life remaining.

Note: When the low battery indicator appears, the temporary pacemaker maintains pacing at the current settings, for a minimum of 24 hours, if the settings were at nominal values (see Section 7.1).

If the batteries are removed, no bars are visible in the battery status indicator. The upper screen is visible, but the lower screen is not displayed. The temporary pacemaker continues to pace and sense until insufficient power is available (see Section 4.3).

After the batteries are depleted, the temporary pacemaker shuts down.

3.2.2.3 Lock indicator

The Lock indicator appears when the temporary pacemaker is locked.

If any of the dials are turned or keys are pressed while the temporary pacemaker is locked, the Lock indicator flashes and the Locked message appears in the lower screen (see Figure 24). When the temporary pacemaker is locked, the **RATE**, **A OUTPUT**, and **V OUTPUT** settings, pacing mode selections, or pacing parameters cannot be adjusted until the temporary pacemaker is unlocked. See Section 5.1.2.

Note: The DOO/Emergency key remains active when the temporary pacemaker is locked. If the DOO/Emergency key is pressed when the temporary pacemaker is locked, the temporary pacemaker initiates high-output, dual-chamber asynchronous pacing (DOO for emergency).

3.3 RATE, A OUTPUT, and V OUTPUT parameters

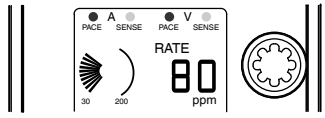
The **RATE**, **A OUTPUT**, and **V OUTPUT** values are displayed both numerically and graphically. The scale next to each numerical value and dial shows the range available for that parameter. Scale segments appear, showing where the parameter is set within the available range. The numerical value for each setting appears to the right of the scale.

3.3.1 RATE

The **RATE** ranges from 30 to 200 ppm (see Figure 11). Turn the **RATE** dial clockwise to increase **RATE** and counterclockwise to decrease **RATE**.

When the temporary pacemaker is turned on, the **RATE** is set to 80 ppm (nominal). See Section 7.1 for the **RATE** increments.

Figure 11. RATE scale, value, and dial



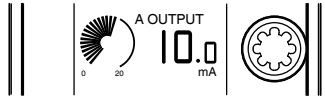
Note: The rate-dependent parameters **UPPER RATE**, **PVARP**, and **A-V INTERVAL** are automatically adjusted each time **RATE** is adjusted unless they are manually set (see Section 5.3.2).

3.3.2 A (Atrial) OUTPUT

The atrial output ranges from 0.1 to 20 mA (see Figure 12). Turn the **A OUTPUT** dial clockwise to increase **A OUTPUT**, or counterclockwise to decrease or turn off **A OUTPUT**. The **A OUTPUT** scale and value are blank when **A OUTPUT** is turned off.

When the temporary pacemaker is turned on, **A OUTPUT** is set to10 mA (nominal). See Section 7.1 for the **A OUTPUT** increments.

Figure 12. A OUTPUT scale, value, and dial



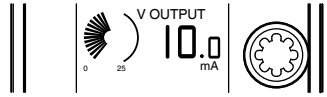
Note: When **A OUTPUT** is turned off manually, both the atrial output and the atrial sensitivity are turned off and there is no atrial pacing or sensing. If **A OUTPUT** is turned back on manually before the temporary pacemaker locks (see Section 5.1.2), atrial sensitivity is set to the previously selected value. If the temporary pacemaker locks after turning off **A OUTPUT**, atrial sensitivity is set to the nominal value of 0.5 mV when **A OUTPUT** is turned back on.

3.3.3 V (Ventricular) OUTPUT

The ventricular output ranges from 0.1 to 25 mA (see Figure 13). Turn the **V OUTPUT** dial clockwise to increase **V OUTPUT** or counterclockwise to decrease or turn off the **V OUTPUT**. The **V OUTPUT** scale and value are blank when **V OUTPUT** is turned off.

When the temporary pacemaker is turned on, **V OUTPUT** is set to 10 mA (nominal). See Section 7.1 for the **V OUTPUT** range increments.

Figure 13. V OUTPUT scale, value, and dial



Note: When **V OUTPUT** is turned off manually, both the ventricular output and the ventricular sensitivity are turned off and there is no ventricular pacing or sensing. If **V OUTPUT** is turned back on manually before the temporary pacemaker locks (see Section 5.1.2), ventricular sensitivity is set to the previously selected value. If the temporary pacemaker locks after turning off **V OUTPUT**, ventricular sensitivity is set to the nominal value of 2.0 mV when **V OUTPUT** is turned back on.

3.4 Lower screen functions

The lower screen has 3 functions:

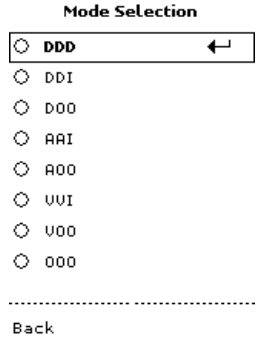
- To select a pacing mode from the Mode Selection menu
- To select and adjust pacing parameters from a Pacing Parameters menu
- To display warnings and instructions

3.4.1 Pacing mode selection

The Mode Selection menu is used to select dual chamber pacing modes (DDD, DDI, or DOO), single chamber pacing modes (AAI, AOO, VVI, or VOO), or no pacing therapy (OOO). See Section 5.1.6.

When the Mode Selection menu is displayed, use the Up or Down arrow keys to highlight a pacing mode with the selection indicator (see Figure 14). Press the Enter key to select the pacing mode.

Figure 14. Mode Selection menu



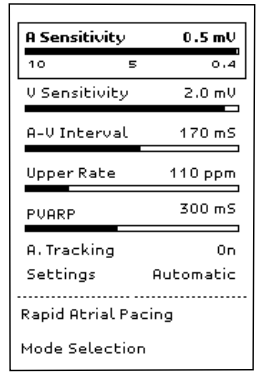
Access the Mode Selection menu using one of the following methods:

- Turn on the temporary pacemaker using the On/Off key
- Select **Mode Selection** from a Pacing Parameters menu (see Figure 15)

3.4.2 Pacing Parameters menu

The Pacing Parameters menu is used to access and adjust the pacing parameters for the selected pacing mode, to select the Rapid Atrial Pacing (RAP) screen, or to navigate to the Mode Selection menu (see Figure 15).

Figure 15. Pacing Parameters menu



See Section 5.1.6, Section 5.3, and Section 5.5 for additional information about pacing parameters, RAP, and the Mode Selection menu.

Note: The Pacing Parameters menu only provides access to the parameters for the selected pacing mode. Not every pacing parameter is accessible for each pacing mode.

4 Preparation for use

4.1 Checks prior to use

4.1.1 Cleaning and disinfection prior to use

During normal use, the temporary pacemaker and cables can be contaminated. Verify that the temporary pacemaker is cleaned and disinfected before each use for a new patient. See Section 6.1 for instructions on cleaning and disinfecting the temporary pacemaker.

Verify that the reusable cables are cleaned and sterilized before each use for a new patient.

Note: For information about cleaning and sterilizing the reusable cables, refer to the applicable technical manual.

Caution: Clean and disinfect the temporary pacemaker before each use for a new patient. Clean and sterilize the reusable cables before each use for a new patient.

4.1.2 Service condition

Check the temporary pacemaker and reusable cables before each use for a new patient to verify that there are no observable defects. Do not use the temporary pacemaker or the reusable cables if there are any observable defects. Verify that the temporary pacemaker controls function and that the battery drawer closes.

Visually inspect the reusable cables and connectors. Do not use the reusable cables if they are damaged. Damage includes, but is not limited to, deterioration of the cable insulation, brittleness, cracking, thinning, or bare spots. Do not use the reusable cables if the conductive wires are exposed.

Caution: Before each use, evaluate the temporary pacemaker for damage and observable defects. Do not use the temporary pacemaker if the case is cracked, the controls are not functioning, the displays are not working, or if the controls, displays, or connectors are broken. If the temporary pacemaker has any observable defects, contact Medtronic at the telephone number on the back cover of this manual for service.

4.2 Physical features

4.2.1 Batteries

Battery drawer – The battery drawer, on the bottom of the temporary pacemaker, accepts two LR6-sized (AA-sized) alkaline batteries (see Section 7.1).

Battery life – The battery life is 7 days minimum with continuous operation for an alkaline battery when the **RATE** is set at 80 ppm and all other parameters are at nominal values (see Section 7.1).

Note: After 6 days, or when the battery status displays 1 bar, the low battery status indicator flashes. When the low battery indicator flashes, the temporary pacemaker has 24 hours of battery life remaining.

Battery drawer latch release button – The battery drawer latch release button at the bottom of the temporary pacemaker opens the battery drawer when it is pressed.

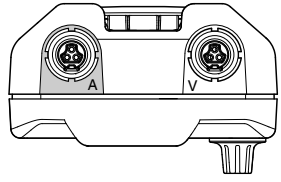
Continued operation after the batteries are removed – If the batteries are removed, the temporary pacemaker continues to operate for 30 s, minimum (see Section 7.1), under the following conditions: **RATE** of 80 ppm or less, **A OUTPUT** and **V OUTPUT** of 10 mA or less, backlight off, and lower screen blank.

Note: The temporary pacemaker may shut down immediately, depending upon the battery level, if the batteries are removed while it is turned on.

4.2.2 Connector block

The connector block, at the top end of the temporary pacemaker, has sockets that accept patient and/or surgical cables. Chamber designations are marked A for atrium and V for ventricle (see Figure 16). The sockets are also color-coded blue for atrium and white for ventricle.

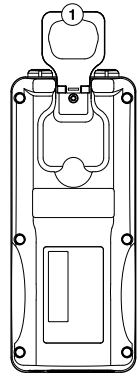
Figure 16. Temporary pacemaker connector block



4.2.3 IV pole hanger

The Medtronic Model 53921 IV pole hanger is attached to the back of the temporary pacemaker and is used to hang the temporary pacemaker on an IV pole (see Figure 17). Fold the IV pole hanger flat against the back of the temporary pacemaker when it is not in use.

Figure 17. IV pole hanger



1 IV pole hanger

Note: If the Medtronic Model 53921 IV pole hanger requires replacement, contact your Medtronic sales or service representative.

4.3 Batteries

Warning: Properly ground all line-powered equipment used on the patient or in the vicinity of the patient (see Section 2.1).

Caution: Monitor the patient's ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during pacing lead insertion and pacemaker connection.

The temporary pacemaker uses two LR6–sized (AA–sized) alkaline batteries for operation (for example, Duracell MN1500 or Eveready E91 batteries).

Cautions:

- Only install the recommended batteries in the temporary pacemaker. Batteries with different physical dimensions, non-alkaline (e.g., lithium or rechargeable) or batteries with contamination on the battery terminals, may result in erratic operation of the temporary pacemaker, no pacing output, or damage to the temporary pacemaker, specifically to the battery compartment.
- Inspect battery terminals for contamination. Using batteries with contaminated terminals can result in the temporary pacemaker turning off, decreased battery life, or corrosion to the battery compartment.

When installing, replacing, or checking the battery status, verify the following items:

- Check the battery status regularly while the temporary pacemaker is in use.
- Verify that the low battery indicator is not flashing.

Remove the batteries when the temporary pacemaker is not in use.

4.3.1 Battery installation recommendations

Verify the following when installing batteries in the temporary pacemaker:

- Install only the recommended batteries. Using non-recommended batteries may result in less than 24 hours of battery life after the low battery indicator illuminates, degraded pacemaker performance, and/or overall reduced battery life.
- Install fresh LR6-sized (AA-sized) alkaline batteries.
- Install the batteries with proper polarity. The temporary pacemaker does not turn on or provide pacing therapy with incorrect battery polarity.

4.3.2 Battery replacement recommendations

Replace the temporary pacemaker batteries in the following situations:

- Replace the batteries for each new patient.
- Replace the batteries when the low battery indicator flashes during temporary pacemaker operation (see Section 3.2.2.2).
- Replace the batteries at least once every week when the temporary pacemaker is in continuous use.

Note: When the low battery indicator flashes, the temporary pacemaker maintains pacing at the current settings for a minimum of 24 hours, if the settings were at nominal values (see Section 7.1).

Caution: Medtronic does not recommend replacing the batteries while the temporary pacemaker is turned on or actively pacing the patient. However, if during an emergency situation the batteries must be replaced while the temporary pacemaker is in use, ensure that the temporary pacemaker is locked before replacing the batteries. Pacing is maintained at the current settings for 30 s, minimum, if the settings are at nominal values (see Section 7.1).

4.3.3 Battery polarity

The temporary pacemaker requires proper battery polarity for operation. Ensure that the batteries align with the polarity markings on the inside of the battery drawer.

The temporary pacemaker does not turn on when batteries are installed with incorrect polarity. If the batteries are replaced while the temporary pacemaker is turned on and the battery polarity is incorrect, the temporary pacemaker continues to pace and sense until insufficient power is available. The low battery indicator continues to flash, and pacing is maintained at the current settings for 30 s minimum, with the settings at nominal values. When internal reserve power is depleted, the temporary pacemaker shuts down.

When the new, fresh batteries are installed with proper polarity in the temporary pacemaker, the following occurs:

- The low battery indicator stops flashing.
- The battery status indicator displays full battery power.

When the batteries are installed with incorrect polarity, the following occurs:

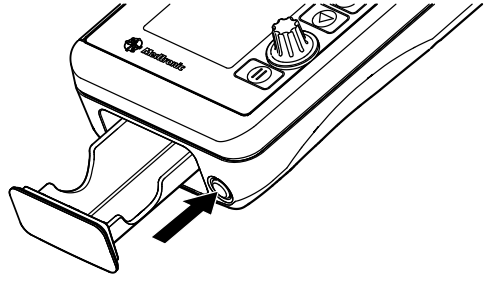
- If the temporary pacemaker is turned off, it does not turn on.
- If the temporary pacemaker is turned on, the low battery indicator continues to flash. The temporary pacemaker continues to pace and sense until internal reserve power is depleted. When internal reserve power is depleted, the temporary pacemaker shuts down.

4.4 Battery installation and replacement

To install (or replace) the batteries, do the following:

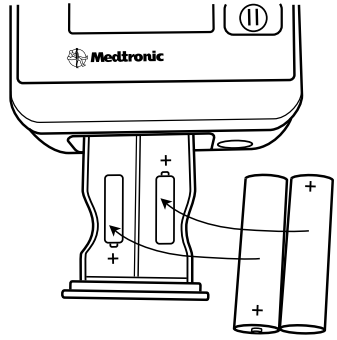
1. Press the battery drawer latch release button until the battery drawer opens (see Figure 18).

Figure 18. Battery drawer latch release button



2. Remove the old batteries.
3. Install two new LR6-sized (AA-sized) alkaline batteries. Verify that the batteries align with the polarity markings on the inside of the battery drawer (see Figure 19).

Figure 19. Installing the batteries with proper polarity



Caution: Ensure that the new, fresh batteries are installed with the correct battery polarity by verifying that the batteries align with the polarity markings on the inside of the battery drawer. The temporary pacemaker requires proper battery polarity for operation. After installing the batteries, ensure that the battery status indicator displays full battery power and that the low battery indicator is not flashing. The temporary pacemaker may temporarily continue to pace and sense with weak, dead, or incorrectly installed batteries.

4. Close the battery drawer firmly until the battery drawer is fully latched.

   Note: Failure to close the battery drawer completely can result in the battery drawer opening and the temporary pacemaker shutting down.

5. Discard the old batteries properly according to local regulations.

4.5 Connector Setup

4.5.1 Using the cables with the temporary pacemaker

Before connecting the cables to the temporary pacemaker, verify the following:

- The reusable cables are supplied non-sterile. Clean and sterilize them before each use. Refer to the applicable technical manual for cleaning, disinfecting, and sterilizing instructions.
- Carefully inspect the reusable cables for visible signs of wear or damage before connecting them to the temporary pacemaker. Do not use the reusable cables if they appear damaged. Damage includes, but is not limited to, deterioration of the cable insulation, brittleness, cracking, thinning, or bare spots. Do not use the reusable cables if the conductive wires are exposed.
- Do not connect the temporary pacemaker to the lead system if it is turned on and is operating at an output amplitude that could cause capture.

Warnings:

- Before connecting the cables to the temporary pacemaker, verify that it is turned off.
- Connect the cables to the temporary pacemaker before connecting the leads to the cables.
- To prevent pacing into the vulnerable period of the T-wave, turn on the temporary pacemaker and turn down A OUTPUT and V OUTPUT to the minimum amplitude before connecting the temporary pacemaker to the patient's lead system. Determine sensing thresholds before turning up A OUTPUT and V OUTPUT to threshold levels.

Cautions:

- When mechanical support is necessary, hang the temporary pacemaker by the IV pole hanger from an IV pole. Do not hang the temporary pacemaker to an IV pole by the cables.
- Avoid contaminating areas that are difficult to clean on the temporary pacemaker. Keep hands and gloves free of blood and body fluids when connecting or disconnecting the patient cables, surgical cables, and/or pacing leads to the temporary pacemaker.

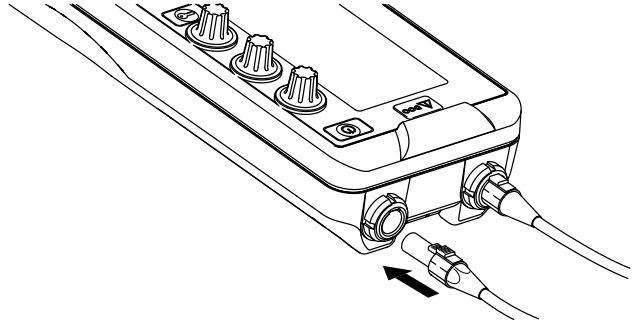
4.5.2 Connecting the cables to the temporary pacemaker

To connect the cables to the temporary pacemaker, do the following:

1. Verify that the temporary pacemaker is turned off.
2. Plug the patient cables or a pair of surgical cables into appropriate sockets on the connector block on top of the temporary pacemaker. One socket is marked A (atrium); the other is marked V (ventricle).
3. Verify that each cable clicks when it is inserted into the temporary pacemaker connector receptacle (see Figure 20).

   Note: The audible click verifies that the plug is completely inserted into the receptacle.

   Figure 20. Connecting the cables to the temporary pacemaker



4. To ensure a good connection, pull gently on the cables after insertion.
5. Connect the leads to the appropriate cable. Match positive (+) and negative (–) leads to positive (+) and negative (–) sockets or clips for the atrium and ventricle (not shown).

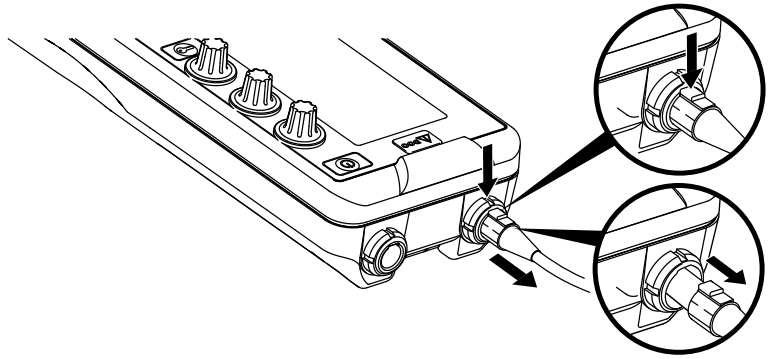
Refer to the applicable patient cable or surgical cable technical manual for more information.

4.5.3 Disconnecting the cables from the temporary pacemaker

To disconnect the cables from the temporary pacemaker, do the following:

1. Set the controls of the temporary pacemaker to allow the patient's intrinsic rhythm to take over pacing. See Section 5.1.3.
2. Press the connector release button on the cable plug (see Figure 21).
3. Gently pull the plug from the receptacle.

Figure 21. Disconnecting the cable from the temporary pacemaker



Refer to the applicable patient cable or surgical cable technical manual for more information.

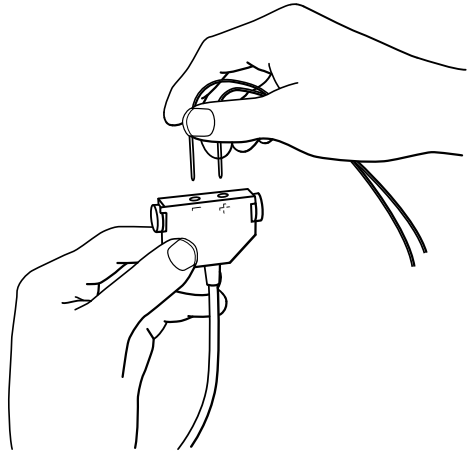
4.5.4 Connecting the pacing lead system to the patient cables

Caution: Unipolar lead systems are not recommended because they are more susceptible to electromagnetic interference, which may result in inappropriate pacing. Unipolar lead systems should not be used in the dual-chambered pacing modes because the current path of one lead system may interfere with the current path of the other.

To connect the pacing lead system to the patient cables, do the following:

1. Loosen the patient cable connector knobs by twisting each knob counterclockwise until resistance is felt.
2. Insert the lead connector pins into the patient cable receptacles as shown (see Figure 22).
3. Verify that each lead system is connected to the appropriate patient cable (atrial or ventricular).
4. Rotate each patient cable connector knob clockwise until finger tight.
5. Gently pull on each lead conductor to verify secure connection.

Figure 22. Connecting the pacing lead system to the patient cable receptacles



Refer to the applicable patient cable technical manual for more information.

4.5.4.1 For bipolar systems

Insert each connector pin into the appropriate receptacle (marked + and –). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections.

Refer to the applicable patient cable technical manual for more information.

4.5.4.2 For single chamber unipolar systems (1-lead systems)

To connect single chamber unipolar lead systems to the temporary pacemaker, perform the following:

1. Insert the cardiac lead connector pin into the negative (–) receptacle of the cable.
2. Insert the connector pin of the “indifferent” electrode (or “ground”) into the positive (+) receptacle of the cable.

Refer to the applicable patient cable technical manual for more information.

4.5.4.3 For dual chamber unipolar systems (2-lead systems)

To connect dual chamber unipolar lead systems to the temporary pacemaker, perform the following:

1. Insert the connector pin of each cardiac lead into the negative (–) receptacle of the appropriate cable.
2. Insert the connector pin of the indifferent electrode into the positive (+) receptacle of one patient cable.
3. Connect the indifferent electrode to the positive receptacle of the second patient cable with a jumper cable.

   Note: The temporary pacemaker will not pace or sense in the chamber if the positive receptacle of the second patient cable is not connected with a jumper cable.

Refer to the applicable patient cable technical manual for more information.

4.6 Placement during use

When the temporary pacemaker is in use, place it in an area that reduces potential unauthorized access from patient interaction or tampering by non-medical personnel.

To reduce potential unauthorized access to the temporary pacemaker when it is in use, do one or more of the following:

- Verify that the temporary pacemaker is directly observable by medical staff.
- Secure the Medtronic Model 53922 Disposable Cover over the temporary pacemaker to prevent inadvertent adjustment of the pacing modes or pacing parameters.
- Hang the temporary pacemaker by either the IV pole hanger or the attachment panel of the disposable pouch to an IV pole.

Caution: Tampering with programmed parameters may have direct and serious patient health effects.

5 Instructions for use

5.1 Basic operation

5.1.1 Turning on or turning off the temporary pacemaker

To turn on the temporary pacemaker, press and hold the On/Off key momentarily.

When the temporary pacemaker turns on, the following occurs: a self-test is initiated. When the self-test completes successfully, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing in both chambers (DDD pacing mode).

- The upper screen and the backlight illuminate.
- A self-test is initiated (see Section 9.1.1).
- The temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing in both chambers (DDD pacing mode).

Warning: To prevent pacing into the vulnerable period of the T-wave, turn on the temporary pacemaker and turn down A OUTPUT and V OUTPUT to the minimum amplitude before connecting the temporary pacemaker to the patient's lead system. Determine sensing thresholds before turning up A OUTPUT and V OUTPUT to threshold levels.

To turn off the temporary pacemaker, do the following:

1. Unlock the temporary pacemaker if it is locked (see Section 5.1.2).
2. Press the On/Off key once. A message is displayed in the lower screen to confirm temporary pacemaker shutdown (see Figure 23).
3. Press the Enter key once within 30 s to confirm temporary pacemaker shutdown.

Note: If the Enter key is not pressed, the temporary pacemaker remains on and continues to pace at the currently selected values.

Figure 23. Temporary pacemaker shutdown message

Notes:

- See Section 7.1 for nominal values when the temporary pacemaker is turned on.
- If the temporary pacemaker fails the self-test, it remains on but does not pace.
- If the batteries are nearing depletion, a red backlight begins flashing behind the battery status indicator, indicating that the batteries have approximately 24 hours or less of battery life. If the batteries are depleted, the LEDs may flash momentarily (see Section 3.2.1) when the On/Off key is pressed, but the temporary pacemaker does not operate.

5.1.2 Lock/Unlock

The Lock/Unlock key locks the temporary pacemaker to prevent inadvertent adjustment of the parameters, or unlocks the temporary pacemaker when it is locked (see Section 3.1.7).

Note: The DOO/Emergency key does not lock.

The temporary pacemaker locks when one of the following occurs:

- 60 s elapses after the last parameter adjustment is made
- When the Lock/Unlock key is pressed

When the temporary pacemaker locks, the following occurs:

- The **RATE**, **A OUTPUT**, and **V OUTPUT** parameter values lock and cannot be adjusted.
- Pacing therapy continues to be delivered at the currently selected values.
- The Lock indicator appears in the upper screen.

- The lower screen does not appear. The Mode Selection options and pacing parameters cannot be adjusted.
- The Pause key is locked.

Notes:

- If any parameter dials are adjusted or any keys are pressed while the temporary pacemaker is locked (other than the DOO/Emergency key), the Lock indicator flashes, and the lower screen displays the Locked message for approximately 30 s (see Figure 24).
- If the DOO/Emergency key is pressed while the temporary pacemaker is locked, the temporary pacemaker begins asynchronous pacing (see Section 5.1.9).

Figure 24. Locked message

Press the Lock/Unlock key to unlock the temporary pacemaker if it is locked.

When the temporary pacemaker unlocks, the following occurs:

- The Lock indicator disappears.
- Pacing therapy continues to be delivered at the currently selected values.
- The **RATE**, **A OUTPUT**, and **V OUTPUT** pacing parameters unlock and can be adjusted.
- The lower screen appears. The Mode Selection options and pacing parameters can be adjusted.
- The Pause key is unlocked.

5.1.3 Viewing the patient's intrinsic rhythm

There are two methods for viewing the patient's intrinsic rhythm.

Recommended method – Reduce the **RATE** gradually, while watching the ECG, until the patient's intrinsic rhythm takes over pacing.

Pause key method – Press and hold the Pause key and watch the ECG. The patient's intrinsic rhythm is viewable on the ECG.

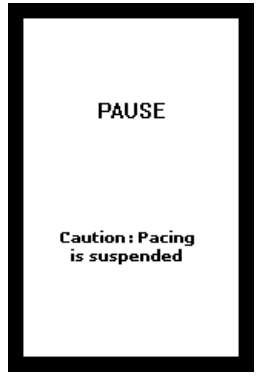
5.1.3.1 Pausing pacing and sensing

Press and hold the Pause key to suspend pacing for up to 10 s (see Section 3.1.11). For the safety of the patient, when the Pause key is pressed and held, pacing is only suspended for 10 s before timing out.

Caution: Use the Pause key with care. The patient receives no pacing support (for a maximum of 10 s at a time) when the Pause key is pressed and held.

When the Pause key is pressed and held, the message shown in Figure 25 appears in the lower screen.

Figure 25. Caution: Pacing is suspended message



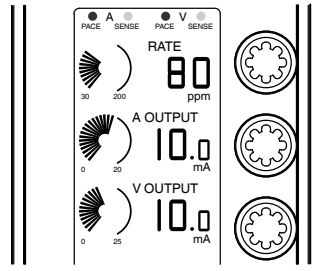
When the Pause key is released or pause times out at 10 s, the temporary pacemaker resumes pacing at the programmed parameters.

Note: To pause again (up to 10 s), release the Pause key, and then press and hold the Pause key again (this is a safety feature).

5.1.4 RATE and OUTPUT adjustments

Use the dials next to the upper screen to adjust the pacing rate, atrial output, and ventricular output. The upper screen displays a numerical value and segmented circular scale that reflects the current setting for each dial. See Figure 26.

Figure 26. RATE and OUTPUT



To adjust **RATE**, **A (Atrial) OUTPUT**, or **V (Ventricular) OUTPUT**, turn the RATE, A OUTPUT, or V OUTPUT dials clockwise to increase their values; turn the dials counterclockwise to decrease their values, or to set the outputs to off.

See Section 7.1 for **RATE**, **A OUTPUT**, or **V OUTPUT** ranges.

5.1.5 Pacing setup

The temporary pacemaker can be set to a single chamber pacing mode (AOO, VOO, AAI, VVI), a dual chamber pacing mode (DDD, DDI, DOO), or no pacing mode (OOO).

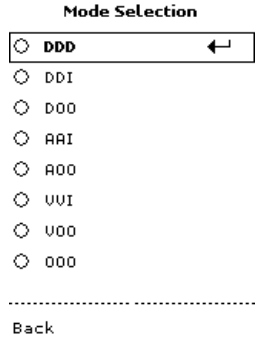
Select the appropriate pacing mode from the Mode Selection menu. The pacing mode can also be set by adjusting **A OUTPUT** or **V OUTPUT** from the upper screen, and **A Sensitivity**, **V Sensitivity** and/or **A. Tracking** from the Pacing Parameters menu.

The pacing information tables (see Section 7.2) provide a quick reference for selecting a pacing mode. Refer to “Basic operation” (see Section 5.1) and “Pacing parameter adjustments” (see Section 5.3) for step-by-step instructions on how to adjust output and sensitivity.

5.1.6 Mode Selection menu

The Mode Selection menu (see Figure 27) is used to select pacing modes or to navigate to the Pacing Parameters menu (see Section 5.3). Use the Up and Down arrow keys to select dual chamber pacing modes (DDD, DDI, and DOO), single chamber pacing modes (AAI, AOO, VVI, and VOO), no pacing mode (OOO), or the Pacing Parameters menu (Back).

Figure 27. Mode Selection menu



The Pacing Mode indicator in the upper screen displays the selected mode. The new mode is activated within the next two cardiac cycles.

If no timing violations occur, the new pacing mode retains the current setting of all applicable parameters of the previous pacing mode. If timing violations occur, the rate-dependent parameters are set to automatic values (see Section 5.4).

Caution: Do not configure the temporary pacemaker in dual chamber mode unless both channels are connected to the heart. If the temporary pacemaker is configured in a dual chamber mode and one of the channels is not connected, the open channel could pick up unintended noise. The noise can be interpreted as a sensed event and can lead to events such as, but not limited to, asynchronous ventricular pacing, pacemaker mediated tachycardia, or ventricular tachycardia.

5.1.6.1 Pacing mode selection

To select a pacing mode, perform these steps:

1. Navigate to the Mode Selection menu.
2. Press the Up or Down Arrow keys to highlight a pacing mode.
3. Press the Enter key to select the pacing mode.

RATE, **OUTPUT** values, and **Sensitivity** values are set to the nominal values when a pacing mode is selected unless they have been manually adjusted before the pacing mode was selected. If they have been manually adjusted before the pacing mode was selected, the new pacing mode retains these values.

For example, if you change from AAI to DDD pacing mode, the value for **A OUTPUT** is retained; **V OUTPUT** is set to the nominal value.

Note: Manually set pacing parameter values are not retained when the temporary pacemaker is turned off and then turned back on.

5.1.7 Synchronous (demand) pacing

During synchronous (demand) pacing, output is inhibited when the pacemaker senses intrinsic activity to minimize competition between the paced rhythm and the intrinsic activity of the heart.

Note: Determine sensitivity and stimulation thresholds (see Section 5.2); otherwise asynchronous pacing, and/or loss of heart capture may occur.

Select one of the pacing modes in Table 1 from the Mode Selection menu to initiate demand pacing.

Table 1. Pacing modes with demand pacing

Synchronous (demand) pacing type	Pacing mode	Result
Dual chamber	DDD, DDI	Pacing and sensing occurs in both chambers.
Atrium	AAI	Pacing and sensing occur only in the atrium. No pacing or sensing occurs in the ventricle.
Ventricle	VVI	Pacing and sensing occur only in the ventricle. No pacing or sensing occurs in the atrium.

5.1.8 Asynchronous pacing

Patients best suited for asynchronous (non-sensing) modes have one of the following issues:

- An intrinsic rate consistently below the pacing rate.
- No intrinsic activity.

Caution: Because it may compete with the intrinsic activity of the heart, asynchronous pacing may result in tachyarrhythmia. Use caution when setting the device to asynchronous modes.

Initiate asynchronous pacing by pressing the DOO/Emergency key or selecting an asynchronous pacing mode from the Mode Selection menu.

Select one of the pacing modes in Table 2 from the Mode Selection menu to initiate asynchronous pacing.

Table 2. Asynchronous pacing types and modes

Asynchronous pacing type	Pacing mode	Result
Dual chamber	DOO	Pacing occurs in the atrium and ventricle. No sensing occurs. Adjust **A OUTPUT** and **V OUTPUT** to provide adequate safety margins to ensure capture (see Section 5.2.3.2).
Atrium	AOO	Pacing occurs only in the atrium. No sensing occurs. Adjust **A OUTPUT** to provide an adequate safety margin (see Section 5.2.3.2).
Ventricle	VOO	Pacing occurs only in the ventricle. No sensing occurs. Adjust **V OUTPUT** to provide an adequate safety margin (see Section 5.2.3.2).

Note: Determine the patient's stimulation threshold; otherwise loss of heart capture may occur (see Section 5.2.3.1).

5.1.8.1 Terminating asynchronous pacing

To terminate asynchronous pacing and to return to synchronous (demand) pacing, perform one of the following actions:

- Press the Enter key, if the DOO/Emergency key was pressed (see Section 5.1.9.2).
- Select a pacing mode with synchronous (demand) pacing from the Mode Selection menu.

5.1.9 Emergency pacing

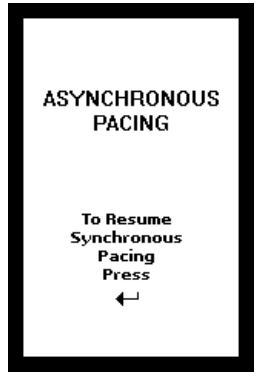
The emergency pacing feature is used to select high-output, dual-chamber asynchronous pacing (DOO for emergency). See Section 7.1 for emergency pacing values.

5.1.9.1 Initiating emergency pacing

Press the DOO/Emergency key to initiate emergency pacing (e.g., dual chamber asynchronous pacing) immediately at maximum output levels (see Section 3.1.2). Emergency pacing is initiated whether the temporary pacemaker is turned on or off, locked, or unlocked.

When the DOO/Emergency key is pressed, the Asynchronous pacing message is displayed in the lower screen (see Figure 28).

Figure 28. Asynchronous pacing message



Adjust the **RATE**, **A OUTPUT**, and **V OUTPUT** by turning the 3 upper dials clockwise or counterclockwise.

5.1.9.2 Terminating emergency pacing

Press the Enter key to terminate emergency pacing and to resume demand pacing (e.g., dual chamber synchronous pacing).

When emergency pacing is terminated and synchronous pacing resumes, the following occurs:

- The **RATE** value remains at the current setting, or at 80 ppm if the temporary pacemaker was turned off before the DOO/Emergency key was pressed.
- **A OUTPUT**, and **V OUTPUT** values remain at the emergency pacing values or at the values set during emergency pacing (if the values were manually adjusted).
- **A SENSITIVITY** and **V SENSITIVITY** return to their nominal values.
- The temporary pacemaker is set to DDD pacing mode, unless **A OUTPUT** or **V OUTPUT** have been turned off during emergency pacing. If **A OUTPUT** has been turned off during emergency pacing, the temporary pacemaker is set to VVI pacing mode after emergency pacing is terminated. If **V OUTPUT** has been turned off during emergency pacing, the temporary pacemaker is set to AAI pacing mode after emergency pacing is terminated.

5.2 Thresholds

Threshold values are needed to determine the appropriate settings for output and sensitivity. Procedures for finding atrial and ventricular sensing and stimulation thresholds are described in this section.

Note: To reduce the risk of competitive pacing, determine the sensing thresholds first, if the patient's intrinsic rhythm is adequate.

5.2.1 Sensing definitions

The ECG in Figure 29 shows the intrinsic beats mixed with paced beats. The temporary pacemaker detects the heart's own beat and does not deliver a pacing stimulus.

Figure 29. Sensing

The ECG in Figure 30 shows one example of undersensing. The temporary pacemaker does not detect intrinsic activity and thus paces on or between beats.

Figure 30. Atrial undersensing

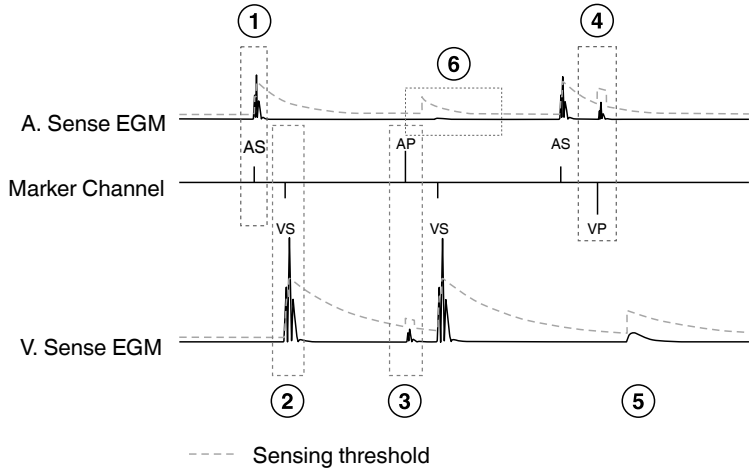
5.2.1.1 Sensing threshold

The sensing threshold is the least sensitive mV setting at which the temporary pacemaker can detect a heartbeat. Monitor the patient's ECG and blood pressure as you follow the procedure to determine the atrial and ventricular sensing thresholds.

5.2.1.2 Automatic adjustment of sensitivity threshold

The temporary pacemaker automatically adjusts the sensing thresholds after certain paced and sensed events to help reduce the oversensing of T-waves, cross-chamber events, and pacing. The threshold adjustment depends on the type of event that precedes the adjustment. During an automatic adjustment, the sensing threshold automatically increases, but it gradually decreases toward the programmed sensitivity value, which is the minimum amplitude that can be sensed. The threshold decrease is intended to be rapid enough to allow subsequent signals to be sensed. An illustration of the sensing threshold adjustment is shown in Figure 31 for nominal values.

Figure 31. Adjustment of sensing thresholds



1 After an atrial sensed event, the temporary pacemaker is temporarily less sensitive to atrial events.
2 After a ventricular sensed event, the temporary pacemaker is temporarily less sensitive to ventricular events.
3 After an atrial paced event, the temporary pacemaker is temporarily less sensitive to ventricular events, but the sensitivity to atrial events remains the same.
4 After a ventricular paced event, the temporary pacemaker is temporarily less sensitive to atrial events.
5 After the post-pace blanking period, the device is temporarily less sensitive to ventricular events.
6 After the post-pace blanking period, the temporary pacemaker is temporarily less sensitive to atrial events.

Note: Automatic adjustment of sensitivity thresholds is limited to certain sensitivity settings.

5.2.1.3 Sensing threshold safety margin

Lead maturation and drug therapy can affect the sensing threshold. To ensure sensing and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **A Sensitivity** and **V Sensitivity** to values that are at least one-half to one-third of the sensing threshold values. For example, an appropriate setting for a patient with a 5.0 mV sensing threshold is 2.5 mV or less.

Caution: Avoid selecting a pacing mode that requires sensing if adequate sensing margins cannot be established. A 2:1 safety margin cannot always be achieved due to a low sensing amplitude and/or a high pacing amplitude. If a 2:1 safety margin cannot be achieved, increase monitoring of the patient to verify that the expected therapy is being delivered.

5.2.2 Determining atrial or ventricular sensing thresholds

Caution: Pacing-dependent patients have limited or no intrinsic rate or rhythm. Only use this procedure on patients with adequate intrinsic rhythm.

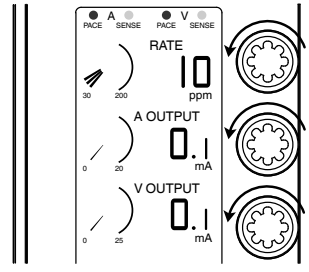
To determine atrial or ventricular sensing threshold, perform the following steps:

1. Turn on the temporary pacemaker without connecting it to the patient lead system.

   Caution: Do not connect the temporary pacemaker to the patient lead system until step 4.

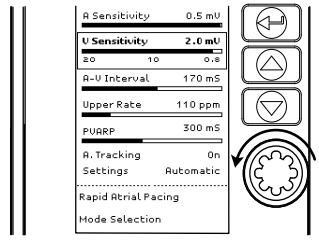
2. Set **RATE** to at least 10 ppm under the patient's intrinsic rate. If necessary, continue to reduce the **RATE** until the temporary pacemaker is not pacing the patient (see Figure 32).
3. Adjust the atrial or ventricular output to prevent the risk of competitive pacing (see Figure 32), as follows:
   - Atrial: Set **A OUTPUT** to 0.1 mA.
   - Ventricular: Set **V OUTPUT** to 0.1 mA.

Figure 32. Decrease RATE, A OUTPUT, and V OUTPUT



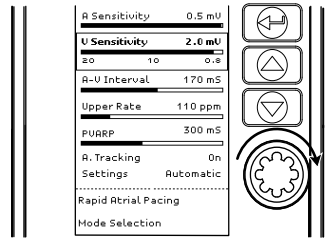
4. Connect the temporary pacemaker to the patient lead system.
5. Navigate to the Mode Selection menu and select the appropriate pacing mode for the patient leads that are connected to the patient.
   - Select DDD pacing mode if both channels are connected.
   - Select AAI pacing mode if only the atrial channel is connected.
   - Select VVI pacing mode if only the ventricular channel is connected.
6. Navigate to the Sensitivity settings.
   a. If the atrial channel is connected, complete steps 7 thru 9 for the **A Sensitivity** setting.
   b. If the ventricular channel is connected, complete steps 7 thru 9 for the **V Sensitivity** setting.
7. Decrease **Sensitivity**: Slowly turn the Menu Parameter dial counterclockwise (increase mV value) until the **SENSE** indicator stops flashing (see Figure 33). The **PACE** indicator flashes continuously, but capture is not likely because the **OUTPUT** value is set to minimum.

Figure 33. Decrease sensitivity



8. Increase **Sensitivity**: Slowly turn the Menu Parameter dial clockwise (decrease mV value) until the **SENSE** indicator starts flashing (see Figure 34). The following occurs:
   - The **PACE** indicator stops flashing.
   - This value is the sensing threshold.

Figure 34. Increase sensitivity



9. Set **Sensitivity** to half (or less) the threshold value. This setting provides at least a 2:1 safety margin.
10. Restore **RATE**, **A OUTPUT**, or **V OUTPUT** to previous values.

Note: Determine the atrial or ventricular stimulation thresholds after determining sensing thresholds.

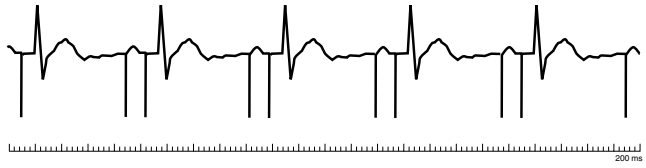
5.2.3 Capture definitions

When a pacing pulse captures the heart, it causes the heart to beat — that is, contract and pump blood. The ECG shows a P-wave or QRS complex after the pulse, as in the example shown in Figure 35.

Figure 35. Capture

When capture is lost, the ECG shows no heart response after the pulse, as in the example shown in Figure 36.

Figure 36. Loss of ventricular capture



5.2.3.1 Stimulation threshold

The stimulation threshold is the minimum output (mA) needed to consistently capture the heart. Monitor the patient's ECG and blood pressure as you follow the procedure to find the atrial and ventricular stimulation thresholds.

5.2.3.2 Stimulation threshold safety margin

Lead maturation and drug therapy can affect the stimulation threshold. To achieve consistent capture and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **A OUTPUT** and **V OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. For example, the appropriate output setting for a patient with a 1.0 mA threshold is 2.0 mA or greater.

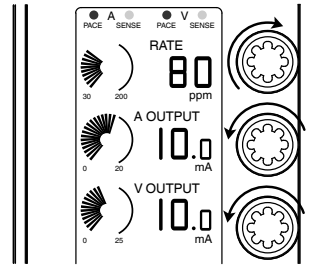
Caution: A 2:1 safety margin cannot always be achieved due to a very high pacing amplitude. If a 2:1 safety margin cannot be achieved, increase monitoring of the patient to verify that the expected therapy is being delivered.

5.2.4 Determining atrial or ventricular stimulation thresholds

To determine atrial or ventricular stimulation thresholds, perform these steps:

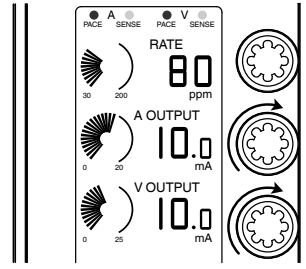
1. Verify that the patient is connected to the temporary pacemaker and is being monitored on the ECG.
2. Set **RATE** at least 10 ppm above the patient's intrinsic rate (see Figure 37).
   If necessary, continue to increase the **RATE** until the temporary pacemaker is pacing the patient. The **PACE** indicator flashes.
3. Decrease **OUTPUT**: Slowly turn the **OUTPUT** dial counterclockwise until the ECG shows loss of capture (see Figure 37).
   The **PACE** and **SENSE** indicators flash intermittently.

Figure 37. Increase RATE, decrease A OUTPUT or V OUTPUT



4. Increase **OUTPUT**: Slowly turn the output dial clockwise until ECG shows consistent capture (see Figure 38). The following occurs:
   - The **PACE** indicator flashes continuously; the **SENSE** indicator stops flashing.
   - This value is the stimulation threshold.

Figure 38. Increase OUTPUT



5. Set **OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. This setting provides at least a 2:1 safety margin.
6. Restore **RATE** to the previous value.

5.3 Pacing parameter adjustments

The Mode Selection menu is used to select different pacing modes. After a pacing mode is selected, the Pacing Parameters menu for that pacing mode is displayed and the parameters can be adjusted (see Figure 39).

The Pacing Parameters menu displays the parameters appropriate for the current pacing mode and allows you to change their values. Depending on the pacing mode, a subset of pacing parameters is displayed. Parameters that do not apply to the current chambers being paced and sensed are not displayed. Parameters that did not apply in the previous mode are set to nominal values in the new mode (see Section 5.6.7).

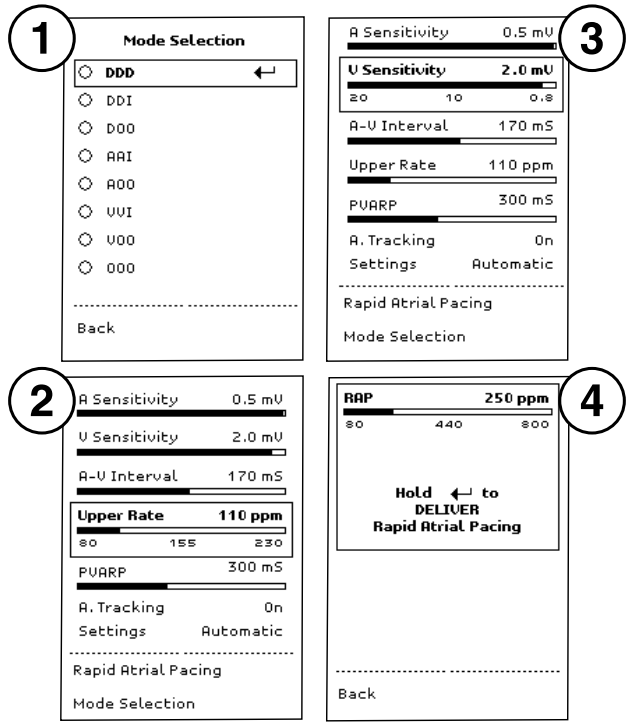
The parameters displayed in a pacing mode are based on the currently programmed pacing mode and rate.

To adjust pacing and sensing parameters, perform the following steps:

1. Select a pacing mode from the Mode Selection menu by pressing the Up or Down Arrow key.
2. Press the Enter key. The pacing parameters for the selected pacing mode are displayed.
3. Press the Up or Down Arrow key to scroll through and select a pacing or sensing parameter.
4. Turn the Menu Parameter dial clockwise or counterclockwise to adjust the value of the selected parameter.

Note: Any value changes to the pacing parameters are not retained when the temporary pacemaker is turned off. All pacing parameters are set to default values when the temporary pacemaker is turned on.

Figure 39. Lower screen pacing parameters



1 Mode Selection menu
2 Upper Rate selected on the DDD Pacing Parameters menu
3 V Sensitivity selected on the DDD Pacing Parameters menu
4 RAP screen

5.3.1 Sensitivity

5.3.1.1 A (Atrial) Sensitivity

Unless manually adjusted, the atrial sensitivity (**A Sensitivity**) is set to the nominal value of 0.5 mV. **A Sensitivity** can be adjusted between 0.4 and 10 mV by turning the Menu Parameter dial, as follows:

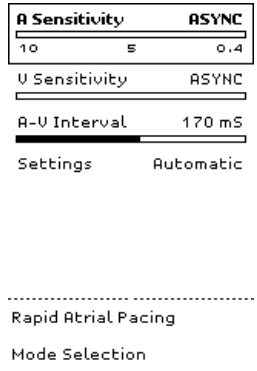
- To increase **A Sensitivity**, turn the dial clockwise (the mV value decreases).
- To decrease **A Sensitivity**, turn the dial counterclockwise (the mV value increases).

The change takes effect within the next two pacing cycles.

To turn off **A Sensitivity** to allow the temporary pacemaker to pace asynchronously in the atrium, turn the Menu Parameter dial counterclockwise until the term **ASYNC** appears (see Figure 40).

Note: When **A Sensitivity** is turned off, a pacing mode change occurs.

Figure 40. A Sensitivity field



The pacing and sensing status bar indicators at the top of the upper screen reflect this change. The **SENSE** indicator under **A SENSE** LED is not displayed, and the **A SENSE** LED no longer flashes.

A Sensitivity is automatically set to **ASYNC** when the following occur:

- The DOO/Emergency key is pressed.
- RAP is delivered.
- DOO pacing mode or AOO pacing mode is selected from the Mode Selection menu.

Note: A Sensitivity is inaccessible when **A OUTPUT** is turned off or in VVI or VOO pacing modes.

5.3.1.2 V (Ventricular) Sensitivity

Unless manually adjusted, ventricular sensitivity (**V Sensitivity**) is set to the nominal value of 2.0 mV.

When selected, the sensitivity can be adjusted between 0.8 and 20 mV by turning the Menu Parameter dial as follows:

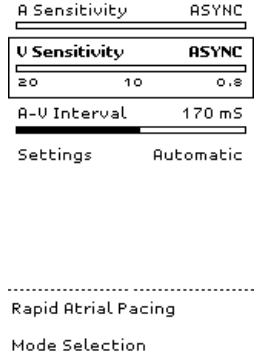
- To increase **V Sensitivity** (the mV value decreases), turn the dial clockwise.
- To decrease **V Sensitivity** (the mV value increases), turn the dial counterclockwise.

The change takes effect within the next two pacing cycles.

To turn off **V Sensitivity** to allow the temporary pacemaker to pace asynchronously in the ventricle, turn the Menu Parameter dial counterclockwise until the term **ASYNC** appears (see Figure 41).

Note: When **V Sensitivity** is turned off, a pacing mode change occurs.

Figure 41. V Sensitivity field



The pacing and sensing status bar indicators at the top of the upper screen reflect the change. The **SENSE** indicator under the **V SENSE** LED is not displayed, and the **V SENSE** LED no longer flashes.

V Sensitivity is automatically set to **ASYNC** when the following occur:

- The DOO/Emergency key is pressed.
- DOO pacing mode or VOO pacing mode is selected from the Mode Selection menu.

Note: V Sensitivity is inaccessible when **V OUTPUT** is turned off or in AAI or AOO pacing modes.

5.3.2 Rate-dependent parameters

A-V Interval, **Upper Rate**, and **PVARP** are rate-dependent parameters. When not manually adjusted, these parameters are automatically set to a factor of the **RATE** (see Section 7.1).

When manually set, the rate-dependent parameters do not change with adjustments to the **RATE**. However, an increase in the **RATE** can cause a timing violation with the **Upper Rate**. Also, a decrease of the **RATE** can cause a timing violation with the **A-V Interval** or **PVARP**. If adjustments to **RATE** cause a timing violation, a warning message appears on the lower screen. The **RATE** cannot be increased until **Upper Rate** is increased or **A-V Interval** and/or **PVARP** are adjusted (see Section 5.4).

5.3.2.1 A-V interval

A-V Interval may be adjusted from 20 to 300 ms in increments of 10 ms.

The **A-V Interval** after an atrial pace (that is, paced atrioventricular interval [PAV], or **A-V Interval**) is the amount of time, in ms, that the temporary pacemaker waits between the delivery of an atrial pacing pulse and delivery of the corresponding ventricular pacing pulse.

Notes:

- The **A-V Interval** after an atrial sensed event [that is, sensed atrioventricular interval (SAV)] is not programmable. The SAV is automatically set to a value 30 ms less than the **A-V Interval** in DDD pacing mode. In DDI pacing mode, SAV = PAV.
- Unless manually adjusted, **A-V Interval** is set to a value determined by the **RATE** setting. It can never be shorter than 50 ms or longer than 250 ms.

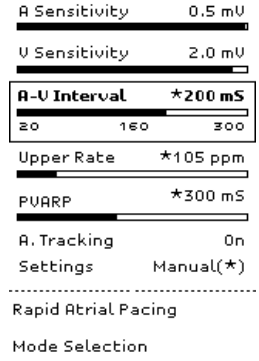
Warning: If **A-V Interval** is set shorter than 50 ms, ventricular events may not be sensed during that interval, due to ventricular blanking after an atrial event.

5.3.2.2 Adjusting A-V interval

To adjust **A-V Interval**, perform the following steps:

1. Navigate to the Pacing Parameters menu.
2. Press the Up or Down Arrow key to select **A-V Interval** (see Figure 42).
3. Turn the Menu Parameter dial clockwise to lengthen the **A-V Interval**, or counterclockwise to shorten the **A-V Interval**.

Figure 42. A-V Interval field



5.3.2.3 Upper Rate

The **Upper Rate** parameter sets the maximum ventricular pacing rate allowed while tracking the atrium. At sensed atrial rates above the **Upper Rate**, a high rate response results (see Section 5.6.6).

Note: The **Upper Rate** parameter is only adjustable in DDD pacing mode.

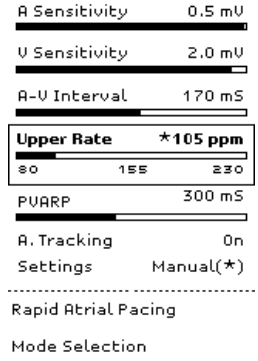
Unless manually adjusted, this parameter is limited to the range of 110 to 230 ppm. When selected on the Pacing Parameters menu, however, the **Upper Rate** can be adjusted to values from 80 to 230 ppm. See Section 7.1.

5.3.2.4 Adjusting Upper Rate

To adjust the **Upper Rate**, perform the following steps:

1. Navigate to the Pacing Parameters menu.
2. Press the Up or Down Arrow key to select **Upper Rate** (see Figure 43).
3. Turn the Menu Parameter dial clockwise to increase the **Upper Rate**, or counterclockwise to decrease the **Upper Rate**.

Figure 43. Upper Rate field



5.3.2.5 Post Ventricular Atrial Refractory Period (PVARP)

The **PVARP** parameter sets the length of time following a ventricular event during which atrial sensing does not affect pacemaker timing. **PVARP** is designed to prevent the temporary pacemaker from responding to atrial sensing of ventricular activities such as far-field R-waves, premature ventricular contractions (PVCs), and retrograde conduction.

Unless manually adjusted, this parameter is determined by the **RATE**. See Section 7.1.

The **PVARP** parameter can be manually adjusted from a minimum value of 150 ms to a maximum value of 500 ms in 10 ms increments so long as the value does not cause a timing violation (see Section 5.4).

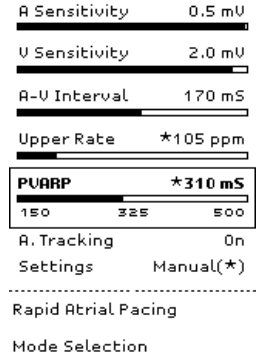
Note: If PVARP is set to the minimum value of 150 ms, atrial events may not be sensed due to the tolerance allowed for blanking after a paced event (see Section 7.1).

5.3.2.6 Adjusting PVARP

To adjust **PVARP**, perform the following steps:

1. Navigate to the Pacing Parameters menu.
2. Press the Up or Down Arrow key to select **PVARP** (see Figure 44).
3. Turn the Menu Parameter dial clockwise to increase the **PVARP**, or counterclockwise to decrease the **PVARP**.

Figure 44. PVARP field



5.3.3 A. Tracking

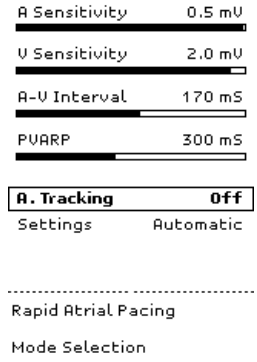
A. Tracking (atrial tracking) is only accessible or applicable when the temporary pacemaker is set to sense and pace in both chambers. When **A. Tracking** is turned **On**, the temporary pacemaker paces the ventricle in synchrony with intrinsic atrial depolarizations.

When **A. Tracking** is turned on (DDD pacing mode), each sensed event on the atrial lead not only inhibits the scheduled atrial pacing pulse, but also triggers an **A-V Interval**.

Warning: If a patient is prone to atrial arrhythmias, atrial tracking could lead to the development of ventricular arrhythmias (see Section 1.7).

When **A. Tracking** is off (DDI pacing mode), an atrial sense will inhibit an atrial pace, but it does not trigger an **A-V Interval** (see Figure 45). The ventricle is paced at the selected **RATE**.

Figure 45. A. Tracking field



5.3.3.1 Turning on or turning off A. Tracking

To turn **A. TrackingOff** or **On**, perform the following steps:

1. Navigate to the Pacing Parameters menu.
2. Press the Up or Down Arrow key until **A. Tracking** is selected.
3. Turn the Menu Parameter dial to change **A. Tracking** from **On** to **Off**. When **A. Tracking** is changed from **On** to **Off**, the following occurs:
   - DDI pacing and sensing begin.
   - The DDI pacing mode indicator appears.
4. Turn the Menu Parameter dial to change **A. Tracking** from **Off** to **On**. When **A. Tracking** is changed from **Off** to **On**, the following occurs:
   - DDD pacing and sensing begin.
   - The DDD pacing mode indicator appears.

Note: A. Tracking can be set to **Off** only from DDD pacing mode and set to **On** only from DDI pacing mode.

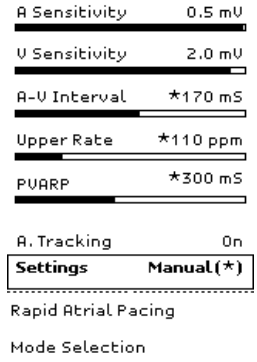
5.3.4 Settings

The **Settings** parameter sets the **A-V Interval**, **Upper Rate**, and **PVARP** to automatic, rate-dependent settings (see Section 7.1).

If **A-V Interval**, **Upper Rate**, or **PVARP** pacing parameters are manually adjusted (in a dual chamber pacing mode), the Pacing Parameters menu displays the following changes:

- **Manual*** appears to the right of **Settings** (see Figure 46).
- An asterisk (*) appears next to the value of each setting that is manually adjusted.

Figure 46. Automatic/Manual Settings field



To change **A-V Interval**, **Upper Rate**, and **PVARP** back to automatic, rate-dependent settings, perform these steps:

1. Navigate to the Pacing Parameters menu.
2. Select **Settings**.
3. Turn the Menu Parameter dial either clockwise or counterclockwise until **Automatic** replaces **Manual**.
4. Use the Menu Parameter dial to alternate between **Automatic** and **Manual** parameter settings, as long as **Settings** remains selected.

Previous **Manual** settings are lost when **Automatic** is selected.

Note: The rate-dependent parameter values are immediately updated on the screen and take effect at the next appropriate event when switching **Settings** from **Automatic** to **Manual**, or **Manual** to **Automatic**.

5.4 Timing violations

If the relationship between two or more parameters reaches a point where improper pacing could occur, further change in the conflicting direction is prevented.

The following sections describe the timing violations.

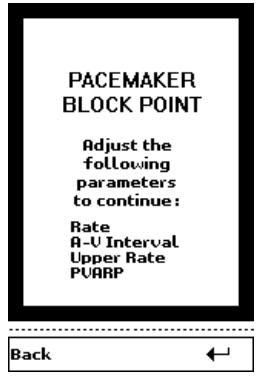
5.4.1 Mode changes

During a pacing mode change, if one or more of the rate-dependent parameters was manually set in the previous pacing mode to a value that causes improper pacing to occur in the new mode, the temporary pacemaker changes the parameter to its automatic, rate-dependent setting.

5.4.2 Parameter adjustments

During adjustments of the rate-dependent parameters, if the parameters are set to values that violate timing rules (e.g., a block point), a warning message is displayed in the lower screen for approximately 30 s, or until the Enter key is pressed. See Figure 47.

Figure 47. Pacemaker Block Point warning message



If the temporary pacemaker reaches a block point, press the Enter key and adjust one of the following pacing parameters:

- **RATE**
- **A-V Interval**
- **Upper Rate**

- **PVARP**
- Select **Settings** and adjust the value to **Automatic** (see Section 5.3.4).

If no adjustments are made, the message disappears after approximately 30 s, and the temporary pacemaker continues to operate at the value selected prior to reaching the block point.

5.4.2.1 Upper Rate versus SAV and PVARP

The total atrial refractory period (TARP), which is SAV Interval + **PVARP**, cannot be longer than the Upper Rate Interval, or the temporary pacemaker reaches the 2:1 block point before being limited by the **Upper Rate**. This condition is prevented by the following formula:

SAV Interval + **PVARP** < **Upper Rate** Interval

Notes:

- DDD pacing mode: SAV Interval = AV Interval - 30 ms
- DDI pacing mode: SAV = PAV

During manual adjustment of **RATE** or the rate-dependent parameters, the temporary pacemaker limits adjustment at the block point and displays the warning message shown in Figure 47.

5.4.2.2 Minimum V-A interval

The V-A interval is the time period elapsing from a ventricular event (sensed or paced) to the next scheduled atrial pace. The minimum V-A interval required by the temporary pacemaker when operating in DOO pacing mode is 70 ms, as defined in the following formula:

A-V Interval + 70 ms ≤ **RATE** interval

Note: RATE interval = **A-V Interval** + V-A interval.

In DOO pacing mode, the temporary pacemaker limits adjustment of **RATE**, or the rate-dependent parameters, at the block point. If the block point is reached, the lower screen displays a warning message (see Figure 47).

Note: This limit only occurs in DOO pacing mode. In DDD and DDI pacing modes, the **RATE** versus **A-V Interval** and **PVARP** block point maintains a 180 ms V-A interval (where V-A interval = 150 ms minimum **PVARP** + 30 ms).

5.4.2.3 RATE versus A-V Interval and PVARP

Mode timing restrictions for atrial sensing are defined with the following formula:

A-V Interval + **PVARP** + 30 ms ≤ **RATE** Interval

If the **RATE** is increased after the rate-dependent parameters are adjusted manually, the temporary pacemaker limits the increase of the **RATE** at the block point. The lower screen displays a warning message (see Figure 47).

5.4.2.4 RATE versus Upper Rate

The **RATE** and **Upper Rate** can be set to the same value. However, the **RATE** cannot be set higher than the **Upper Rate**, the **Upper Rate** cannot be set lower than the **RATE**, and the **Upper Rate** cannot exceed the temporary pacemaker block point.

If any of these adjustments are attempted, the lower screen displays the warning message in Figure 47.

5.5 Rapid Atrial Pacing (RAP)

RAP can be used to interrupt some types of atrial tachycardias or to induce an atrial tachycardia.

Caution: RAP is for atrial use only. Before enabling RAP, be sure that the atrial leads are connected to the atrium, not the ventricle.

5.5.1 Rapid Atrial Pacing (RAP)

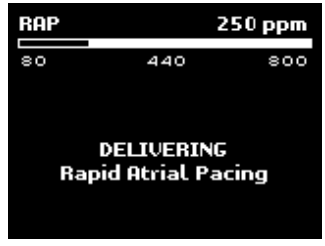
To access the RAP screen, select **Rapid Atrial Pacing** from the Pacing Parameters menu.

The RAP screen displays the **RAP** rate. See Figure 48.

Figure 48. Rapid Atrial Pacing screen

When the Enter key is pressed and held, the temporary pacemaker waits a maximum of two pacing cycles, and then begins pacing asynchronously in the atrium (AOO pacing mode) at the selected **RAP** rate. See Figure 49.

Figure 49. Delivering rapid atrial pacing



Note: The temporary pacemaker does not deliver RAP until the Enter key is pressed and held. **RATE**, **A OUTPUT**, **V OUTPUT** remain at their selected values for the current pacing mode until the Enter key is pressed and held.

5.5.2 Delivering RAP

Caution: RAP may result in tachycardia, acceleration of existing tachycardia, or fibrillation. Apply high rates under careful patient monitoring and control. Monitor the patient's ECG and blood pressure, and ensure that defibrillation equipment is immediately available.

To deliver RAP, perform the following steps:

1. Navigate to the Pacing Parameters menu.
2. Press the Up or Down Arrow key to highlight **Rapid Atrial Pacing** (RAP).

3. Verify that the leads are in contact with the atrium and are connected to the atrial channel of the temporary pacemaker through a patient or surgical cable.
4. Press the Enter key to open the RAP screen.
   The RAP screen displays the RAP rate (initially the rate of 250 ppm). Pacing continues at currently displayed settings.
5. Adjust RAP rate as needed. Turn the Menu Parameter dial clockwise to increase rate, or counterclockwise to decrease rate.

   Note: The range for RAP is 80 ppm to 800 ppm.

6. Press and hold the Enter key to deliver RAP burst.
   AOO pacing begins at displayed RAP rate and current **A OUTPUT**. The **A PACE** LED flashes during delivery of RAP pulses.

   Note: RAP delivery stops when either the Enter key is released, or after 2 min have passed.

To exit the RAP screen, use the Up or Down Arrow key to highlight **Back**, and then press the Enter key.

During the delivery of RAP, the following value settings occur:

- **A OUTPUT** does not lock and may be adjusted during RAP delivery.
- **V OUTPUT** is off and not accessible during RAP delivery. **V OUTPUT** returns to its previous value when the Enter key is released.
- There is no ventricular support during RAP.
- If the Enter key is pressed while **A OUTPUT** is turned off, RAP is delivered at 10 mA. **A OUTPUT** returns to off as soon as the Enter key is released, even if **A OUTPUT** is adjusted during RAP delivery.

5.5.2.1 Adjusting rate or atrial output during RAP delivery

The RAP rate and **A OUTPUT** can be adjusted during RAP delivery by turning the Menu Parameter dial. To adjust the RAP rate and **A OUTPUT**, do the following:

1. Continue to press and hold the Enter key.
2. Turn the Menu Parameter dial clockwise or counterclockwise to adjust RAP rate.
3. Turn the A OUTPUT dial clockwise or counterclockwise to adjust atrial output.

5.5.2.2 Resuming pacing at previous settings

Release the Enter key to resume pacing at the previous settings. The temporary pacemaker stops delivering RAP and resumes operation at the non-RAP settings, within 3 s.

If the **A OUTPUT** is adjusted during RAP, the new setting is retained when RAP is terminated.

Note: When resuming operation in a demand mode, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing in both chambers (DDD pacing mode).

Caution: If the temporary pacemaker continues to deliver RAP after the Enter key is released, press the On/Off key or the DOO/Emergency key to stop RAP. If RAP continues to be delivered, remove the batteries from the temporary pacemaker. Return the temporary pacemaker for service.

5.6 Automatic responses

5.6.1 Blanking periods

Blanking periods follow paced and sensed events and help to prevent the following from occurring:

- Sensing pacing pulses
- Post-pacing depolarization
- T-waves
- Oversensing the same event

The blanking periods after paced events are longer than or equal to those after sensed events to avoid sensing the atrial and ventricular depolarizations (see the specifications in Section 7.1).

5.6.2 Refractory periods

A pacing refractory period is the interval during which a sensed event does not affect pacing timing. During a pacing refractory period, the temporary pacemaker senses normally but classifies sensed events as refractory and limits its response to these events.

A pacing refractory period prevents inappropriately sensed signals, such as far-field R-waves or electrical noise, from triggering certain pacing timing intervals.

The temporary pacemaker has an Atrial Refractory Period (ARP), but does not have a Ventricular Refractory Period (VRP). The initiation of these two types of pacing refractory periods are described below:

Atrial Refractory Period (ARP) – The temporary pacemaker has two types of atrial refractory periods:

- ARP, which is initiated by an atrial sense or pace
- Post Ventricular Atrial Refractory Period (PVARP), which is initiated by a ventricular sense or pace

Ventricular Refractory Period (VRP) – A VRP is initiated by a ventricular pace or sense. The temporary pacemaker does not use a VRP.

5.6.3 Noise response

The temporary pacemaker paces asynchronously at the programmed RATE in the presence of continuous noise (such as 50 Hz or 60 Hz interference) with cycle lengths of 40 ms or less until the noise terminates. This noise response applies to the atrial or ventricular channel or both, depending on the channel for which the noise is sensed.

5.6.4 Wenckebach response

The Wenckebach response occurs during DDD pacing mode. When the intrinsic atrial rate of the patient increases beyond the UPPER RATE, the temporary pacemaker continues to lengthen the SAV interval until a P-wave falls within the PVARP. When the P-wave falls within the PVARP, it is not sensed.

Because the P-wave is not sensed, the SAV interval is not started, and a ventricular pace is not issued.

5.6.5 Ventricular safety pacing

The Ventricular Safety Pacing feature is intended to prevent improper inhibition of ventricular pacing pulses if a non-ventricular event (such as cross-talk or noise) is sensed by the ventricular lead. This feature functions when the temporary pacemaker is operating in a mode that senses and paces in the ventricle, and senses and paces in the atrium (DDI and DDD pacing modes).

If a ventricular sensed event is detected outside the 30 ms blanking window, but within 110 ms after an atrial paced event, a ventricular safety pacing (VSP) pulse is delivered at 110 ms after the atrial pace if the **A-V INTERVAL** is greater than 110 ms. The ventricular pacing pulse is delivered at the **A-V INTERVAL** if the **A-V INTERVAL** is less than 110 ms. If the **RATE** is set to 86 ppm or higher, the values of 110 ms change to 70 ms (see Section 7.1). The **VPACE** LED and the **VSENSE** LED flash within 15 ms of each other.

5.6.6 High atrial rate response

The Mode Switch feature temporarily switches from DDD pacing mode to a nontracking DDI pacing mode upon detection of an atrial tachyarrhythmia (see Figure 50). The programmed DDD pacing mode is restored when the atrial tachyarrhythmia ends. By operating in a nontracking pacing mode, the temporary pacemaker prevents rapid ventricular pacing that may result from a high atrial rate.

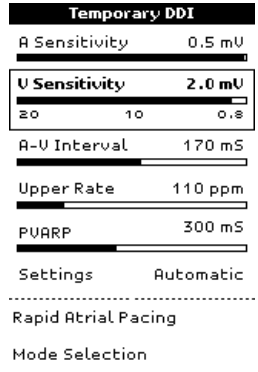
Note: Mode Switch is only available when the temporary pacemaker is operating in DDD pacing mode.

Mode Switch operation starts when the temporary pacemaker detects the onset of an atrial tachyarrhythmia episode. The detection of AT/AF onset is based on the timing of atrial events within the ventricular intervals.

After the temporary pacemaker detects the onset of an atrial tachyarrhythmia, Mode Switch temporarily changes the pacing mode from DDD to a non-atrial tracking DDI pacing mode. The ventricular pacing rate gradually changes from the tracking rate to the base rate. This prevents an abrupt drop in the ventricular rate.

When the atrial tachyarrhythmia ends and the atrial rate decreases below the programmed Upper Rate, Mode Switch changes the pacing mode back to DDD pacing mode.

Figure 50. Temporary DDI pacing mode screen



5.6.7 Pacing mode transitions

The temporary pacemaker switches pacing modes in accordance with the following guidelines:

- When switching from an atrial-only pacing mode to a pacing mode involving an **A-V Interval** (which could be as short as 20 ms), the first ventricular pacing pulse will be inhibited to avoid pacing into a T-wave.
- A complete cycle of the current mode is allowed to expire before implementing a new mode.
- When switching from an asynchronous pacing mode to a synchronous pacing mode, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing in both chambers (DDD pacing mode).
- **Upper Rate** is implemented immediately after switching to DDD pacing mode.
- Parameters that did not apply in the previous mode will be set to nominal (or rate-dependent) values in the new mode.

6 Cleaning, disinfecting, and maintenance

6.1 Cleaning and disinfecting the temporary pacemaker

Cautions:

- Clean and disinfect the temporary pacemaker before each use for a new patient.
- Do not immerse the temporary pacemaker in water or cleaning agents. Severe damage to the temporary pacemaker may occur. Do not use automated machine washers. Do not sterilize the temporary pacemaker by ethylene oxide, gamma radiation or steam-sterilization (autoclave). Damage to the temporary pacemaker may occur using these methods.
  Clean and disinfect the temporary pacemaker before each use for a new patient.
- Remove the batteries prior to cleaning and disinfecting the temporary pacemaker.

Cleaning – Before disinfection, clean the temporary pacemaker thoroughly using a 70% isopropyl alcohol prep pad. Wipe to remove all visible soil or blood. Allow the temporary pacemaker to air dry approximately 5 min or until it is dry.

Disinfecting – Disinfect the temporary pacemaker by using a 70% isopropyl alcohol and a sterile prep pad, gauze pad or sponge. Wipe down all the external surfaces of the temporary pacemaker. Maintain an exposure time (wet or damp time) of 15 min. Allow the temporary pacemaker to air dry for approximately 5 min or until it is dry.

Maintenance – During use, the temporary pacemaker can become too contaminated for effective cleaning or disinfection by the clinic. If the temporary pacemaker has blood or soil ingress in its battery compartment, cable ports, or under the knobs, return it to Medtronic for cleaning and disinfecting. When blood or soil enters into these areas, the clinic cannot effectively clean or disinfect the temporary pacemaker.

Note: Do not expose the temporary pacemaker to ethers, acetone, chlorinated solvents, or disinfectants. These solvents may damage the case, labels, or metal components.

6.2 Safety and technical checks

Perform safety and technical checks on the temporary pacemaker at a minimum of every 12 months, and after any malfunction or accident. Medtronic recommends that qualified engineers and technicians trained in the service of Medtronic products perform the checks. Contact your Medtronic sales or service representative for service or training.

Note: Understanding the warnings listed in this manual is necessary to perform safety and technical checks successfully.

6.2.1 Visual inspection

Perform the following visual inspections each time the temporary pacemaker is used:

- Check that there is no mechanical or physical damage to the temporary pacemaker.
- Inspect the battery compartment and battery connection for corrosion and other contamination.

6.2.2 Functional inspection

Perform the following functional inspections each time the temporary pacemaker is used:

- Verify that the temporary pacemaker passes the self-test at power-up.
- Verify that the front panel dials, keys, and displays function and work properly.
- Inspect all connections and cables. Verify that the patient cables are properly connected and are not damaged.

6.2.3 Practical measurements

Verify the following practical measurements during scheduled safety and technical checks:

- Rate Test
- Rapid Atrial Pacing
- Output
- Sensitivity
- Battery drain test
- Off Current Drain (10 µA maximum)
- On Current Drain with backlight and lower screen off (5.9 mA maximum when measured away from pacing peaks)
- Patient Leakage Current Measurements per IEC 60601-1 and Patient Auxiliary Current Measurements per IEC 60601-2-31.

Caution: Do not open the external case of the temporary pacemaker. Opening the external case of the temporary pacemaker voids the warranty.

Medtronic does not recommend field repair of the device. Contact your local Medtronic sales or service representative for service or repair.

6.3 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative.

Should service or repair be necessary, contact your local Medtronic sales or service representative.

A serial number identifying each individual temporary pacemaker is printed on the back surface of the device. Reference this serial number in any correspondence regarding this device.

6.4 Product useful life

Long-term reliability of the temporary pacemaker is subject to the actual use conditions of the device. The routine testing and preventative maintenance recommended in this manual will help provide reliable operation of the temporary pacemaker.

The expected service life of the temporary pacemaker is five years. Medtronic will not service or repair the temporary pacemaker after five years. Contact your Medtronic representative to replace your temporary pacemaker after it has been in service for five years.

7 Specifications

7.1 Device specifications

Table 3. Temporary pacemaker specifications

Pacing modes	DDD, DDI, DOO, AAI, AOO, VVI, VOO		
RATE	Range (in ppm)	Increments (in ppm)	Tolerance
	30 – 50 50 – 100 100 – 170 170 – 200	5 2 5 6	30 – 200 ±2%
RAP rate	Range (in ppm)	Increments (in ppm)	Tolerance
	80 – 180 180 – 250 250 – 360 360 – 800	20 5 10 20	80 – 360 ±2% 380 – 800 ±4%
Output amplitude			
Atrial	Range (in mA)	Increments (in mA)	Tolerance
	0.1 – 0.4 0.4 – 1.0 1.0 – 5.0 5.0 – 20	0.1 0.2 0.5 1.0	0.1 – 20 Greater of ±0.1 mA or ±10% (200-1000 Ω)
Ventricular	Range (in mA)	Increments (in mA)	Tolerance
	0.1 – 0.4 0.4 – 1.0 1.0 – 5.0 5.0 – 25	0.1 0.2 0.5 1.0	0.1 – 20 Greater of ±0.1 mA or ±10% (200-1000 Ω)
			20 – 25 ±10% (200–500 Ω)
Pulse width (fixed)			
Atrial	1.0 ms ±10%		
Ventricular	1.5 ms ±10%		
Sensitivity[a]			
Atrial	Range (in mV)	Increments (in mV)	Tolerance
	0.4 – 0.8 0.8 – 2.0 2.0 – 3.0 3.0 – 10	0.1 0.2 0.5 1.0	< 0.8 mV ±60% ≥ 0.8 mV ±40%

Table 3. Temporary pacemaker specifications (continued)

Ventricular	Range (in mV)	Increments (in mV)	Tolerance
	0.8 – 1.0 1.0 – 3.0 3.0 – 10 10 – 20	0.2 0.5 1.0 2.0	±55%
A-V Interval			
	Paced A-V (PAV)	Sensed A-V (SAV)	
Formula	300 – (1.67 x RATE in ppm) within range	= PAV – 30 within range in DDD pacing mode = PAV within range in DDI pacing mode	
Range (in ms)	50 – 250 – Auto 20 – 300 – Manual	50 – 250	
Increments (in ms)	10	10	
Tolerance	Greater of ±5 ms or ±5%	Greater of ±15 ms or ±15%	
Refractory period			
Atrial			
At atrial event	SAV or PAV, whichever is in effect		
	310 ms +5/-30 ms or 75% of the base rate, whichever is lower (AAI pacing mode only)		
At ventricular event (PVARP)	Auto (all values are +5/-30 ms)	Rate range (in ppm)	PVARP (in ms)
		≤ 100 > 100 and ≤ 150 > 150 and ≤ 180 > 180	300 250 230 200
	Manual (all values are +5/-30 ms)	Range (in ms)	Increments (in ms)
		150 – 500	10
Upper Rate			
Auto	RATE + 30 ppm ±10%	Minimum of 110 ppm	
Manual	Range (in ppm)	Increments (in ppm)	Tolerance
	80 – 100 100 – 170 170 – 200 200 – 214 214 – 230	2 5 6 7 8	±10%

Table 3. Temporary pacemaker specifications (continued)

Safety pace	RATE < 86 ppm	Occurs 110 ms after atrial pace, if A-V interval is set to more than 110 ms, or at programmed A-V interval if A-V interval is set to less than 110 ms
	RATE ≥ 86 ppm	Occurs 70 ms after atrial pace, if A-V interval is set to more than 70 ms, or at programmed A-V interval if A-V interval is set to less than 70 ms
Mode switch detection rate	= 171 ppm, if the Upper Rate is < 165 ppm = Upper Rate + 10 ppm, if the Upper Rate is ≥ 165 ppm	
Blanking[b]		
Atrial		
200 ms +5/-30 ms – after atrial pace		
100 ms +2/-30 ms – after atrial sense		
100 ms +2/-15 ms – after ventricular pace/sense		
Ventricular		
30 ms +2/-15 ms – after atrial pace		
200 ms +5/-30 ms – after ventricular pace		
120 ms +2/-30 ms – after ventricular sense		
RATE limit (non-RAP)	230 ppm	If a non-RAP rate exceeds 230 ppm, pacing is terminated. A recoverable error message is displayed in the lower screen.
Nominal values - DDD pacing mode		**Nominal values - DOO for Emergency**
Pacing mode	DDD	DOO for Emergency
RATE	80 ppm	When the DOO/Emergency key is pressed, current setting (or 80 ppm if the temporary pacemaker was off before the DOO/Emergency key was pressed).
Output amplitude		
Atrial	10 mA	20 mA for Emergency
Ventricular	10 mA	25 mA for Emergency
Pulse width (fixed)		
Atrial	1.0 ms	
Ventricular	1.5 ms	
Sensitivity		
Atrial	0.5 mV	Asynchronous for Emergency
Ventricular	2.0 mV	Asynchronous for Emergency

Table 3. Temporary pacemaker specifications (continued)

AV Interval		
Sensed	140 ms	
Paced	170 ms	When the DOO/Emergency key is pressed, current manual setting (or 170 ms if temporary pacemaker is off, or automatic rate-dependent when the temporary pacemaker is on)
PVARP	300 ms	Not applicable
Upper Rate	110 ppm	Not applicable
RAP rate	250 ppm	
Dimensions		
Height	20.3 cm (8.0 in) ±15%	
Width	8.6 cm (3.375 in) ±15%	
Depth (without dials)	4.45 cm (1.75 in) ±15%	
Weight (with battery)	680 g (24 ounces) maximum	
Temperature		
Operating	15 °C to 35 °C (59 °F to 95 °F)[c]	
Storage (without battery)	-40 °C to 70 °C (-40 °F to 158 °F)	
Humidity (storage)	> 80% and ≤ 95% at 35 °C (95 °F), use after 48 hours dry time ≥ 10% and ≤ 80% at 35 °C (95 °F), for immediate use	
Battery type	Two IEC type LR6-sized (AA-sized) 1.5 V alkaline batteries (Duracell MN1500, Eveready E91 or equivalent)	
Battery life	7 days minimum, when the RATE is 80 ppm, and all other parameters are at the nominal values. Higher amplitudes and rates decrease battery life.	
Operation after battery removal	30 s (typical) under the following conditions: RATE of 80 ppm or less, A OUTPUT and V OUTPUT of 10 mA or less, backlight off, and lower screen blank.[d]	

[a] When sensing 40 ms-wide Haversine waveform for ventricular inputs, 20 ms-wide Haversine waveform for atrial inputs.
[b] When tested with a 1 ms square pulse with sufficient amplitude.
[c] Within the ranges of 10 °C to 15 °C (50 °F to 59 °F) and 35 °C to 43 °C (95 °F to 110 °F), the specification for OUTPUT is derated an additional ± 5%, the specification for SENSITIVITY is derated an additional ± 7%; and the specification for RATE is not derated.
[d] Medtronic does not recommend replacing the batteries while the pacemaker is turned on or actively pacing the patient.

7.2 Pacing information tables

Table 4. Temporary pacemaker single chamber pacing setup table

Pacing mode	**AOO**	**VOO**	**AAI**	**VVI**
A (Atrial) and V (Ventricle) Indicators	**A**	**V**	**A**	**V**
PACE and SENSE Indicators	PACE	PACE	PACE + SENSE	PACE + SENSE
Instructions				
1. Set OUTPUT				
A OUTPUT	On	Off	On	Off
V OUTPUT	Off	On	Off	On
2. Set Sensitivity				
A Sensitivity	ASYNC	NA	On	NA
V Sensitivity	NA	ASYNC	NA	On
3. Set **A Tracking**	NA	NA	NA	NA

Table 5. Temporary pacemaker dual chamber pacing setup table

Pacing mode	**DOO**	**DDD**	**DDI**
A (Atrial) and V (Ventricle) Indicators	**A+V**	**A+V**	**A+V**
PACE and SENSE Indicators	PACE (A) + PACE (V)	PACE + SENSE (A) and PACE + SENSE (V)	PACE + SENSE (A) and PACE + SENSE (V)
Instructions			
1. Set OUTPUT			
A OUTPUT	On	On	On
V OUTPUT	On	On	On
2. Set Sensitivity			
A Sensitivity	ASYNC	On	On
V Sensitivity	ASYNC	On	On
3. Set **A Tracking**	NA	On	Off

Table 6. Rate and interval conversion chart for RATE and RAP

Rate		**RAP**	
Rate	Interval	Rate	Interval
30 ppm	2000 ms	80 ppm	750 ms
35 ppm	1714 ms	100 ppm	600 ms

Table 6. Rate and interval conversion chart for RATE and RAP (continued)

Rate		**RAP**	
40 ppm	1500 ms	120 ppm	500 ms
45 ppm	1333 ms	140 ppm	429 ms
50 ppm	1200 ms	160 ppm	375 ms
52 ppm	1154 ms	180 ppm	333 ms
54 ppm	1111 ms	185 ppm	324 ms
56 ppm	1071 ms	190 ppm	316 ms
58 ppm	1034 ms	195 ppm	308 ms
60 ppm	1000 ms	200 ppm	300 ms
62 ppm	968 ms	205 ppm	293 ms
64 ppm	938 ms	210 ppm	286 ms
66 ppm	909 ms	215 ppm	279 ms
68 ppm	882 ms	220 ppm	273 ms
70 ppm	857 ms	225 ppm	267 ms
72 ppm	833 ms	230 ppm	261 ms
74 ppm	811 ms	235 ppm	255 ms
76 ppm	789 ms	240 ppm	250 ms
78 ppm	769 ms	245 ppm	245 ms
80 ppm	750 ms	250 ppm	240 ms
82 ppm	732 ms	260 ppm	231 ms
84 ppm	714 ms	270 ppm	222 ms
86 ppm	698 ms	280 ppm	214 ms
88 ppm	682 ms	290 ppm	207 ms
90 ppm	667 ms	300 ppm	200 ms
92 ppm	652 ms	310 ppm	194 ms
94 ppm	638 ms	320 ppm	188 ms
96 ppm	625 ms	330 ppm	182 ms
98 ppm	612 ms	340 ppm	176 ms
100 ppm	600 ms	350 ppm	171 ms
105 ppm	571 ms	360 ppm	167 ms
110 ppm	545 ms	380 ppm	158 ms
115 ppm	522 ms	400 ppm	150 ms
120 ppm	500 ms	420 ppm	143 ms
125 ppm	480 ms	440 ppm	136 ms
130 ppm	462 ms	460 ppm	130 ms
135 ppm	444 ms	480 ppm	125 ms

Table 6. Rate and interval conversion chart for RATE and RAP (continued)

Rate		**RAP**	
140 ppm	429 ms	500 ppm	120 ms
145 ppm	414 ms	520 ppm	115 ms
150 ppm	400 ms	540 ppm	111 ms
155 ppm	387 ms	560 ppm	107 ms
160 ppm	375 ms	580 ppm	103 ms
165 ppm	364 ms	600 ppm	100 ms
170 ppm	353 ms	620 ppm	97 ms
176 ppm	341 ms	640 ppm	94 ms
182 ppm	330 ms	660 ppm	91 ms
188 ppm	319 ms	680 ppm	88 ms
194 ppm	309 ms	700 ppm	86 ms
200 ppm	300 ms	720 ppm	83 ms
		740 ppm	81 ms
		760 ppm	79 ms
		780 ppm	77 ms
		800 ppm	75 ms

8 Special notice

8.1 Special notice for the temporary pacemaker

Use of prior Medtronic temporary pacemakers has met with some success in the treatment of certain heart disorders, including heart block and heart arrhythmias. However Medtronic makes no warranty that the Model 5392 Dual Chamber Temporary External Pacemaker will efficiently restore adequate cardiac function for all patients. For information regarding common causes of pacing difficulty, consult other portions of the manual.

9 Troubleshooting

9.1 Troubleshooting

9.1.1 Self-test

When the temporary pacemaker is turned on, a startup message appears in the lower screen. A self-test is executed while the temporary pacemaker is turning on. The self-test includes a check of all keys and critical internal circuits. The **PACE** and **SENSE** LEDs illuminate to indicate progress during the self-test.

Note: Pressing any key while the self-test is in process can cause the temporary pacemaker to fail the self-test. The temporary pacemaker interprets the pressed key as being “stuck” and, therefore, malfunctioning. If a key is pressed during the self-test, causing a self-test failure, the lower screen displays an error message until the key is released.

The upper and lower screens initialize when the temporary pacemaker turns on. All indicators display, including the low battery indicator, for 2 s. The low battery indicator displaying during the upper screen initialization does not indicate that the batteries are low. If the batteries are low, the low battery indicator remains visible during temporary pacemaker operation.

After successful completion of the self-test, the temporary pacemaker first searches for cardiac activity (during the first pacing cycle), and then begins sensing and pacing in both chambers (DDD pacing mode).

If the temporary pacemaker fails the self-test, the **PACE** and **SENSE** LEDs remain on in a pattern indicating the failed test, and no output pulses are issued. Failure codes may be displayed on the lower screen. Follow the instructions that appear on the screen to restart the temporary pacemaker, or to return the temporary pacemaker for service (contact your Medtronic representative). When returning the temporary pacemaker, remove the batteries, and return both the temporary pacemaker and the batteries.

9.1.2 Loss of sensing

Figure 51. Loss of atrial sensing (DDD pacing mode)

Figure 52. Loss of ventricular sensing (DDD pacing mode)

9.1.2.1 Keys to identifying loss of sensing

If a P-wave or R-wave is present, the temporary pacemaker does not detect intrinsic activity and delivers a pacing pulse. The following occurs:

- Pacing artifacts are seen asynchronously on ECG.
- Sense indicator does not flash, though ECG shows depolarization.

9.1.2.2 Potential causes of loss of sensing

Heart/patient related	Patient cable/lead related	Temporary pacemaker related
Inadequate cardiac signal	• Loose connection at the connector block • Inappropriate lead placement • Insulation break or wire fracture	• Inappropriate sensitivity setting • Inappropriate pacing mode selection • Small sensing window • Electrical noise

9.1.2.3 Potential solutions for loss of sensing

Check one or more of the following when troubleshooting loss of sensing:

- Check cable connections for loose wires.
- Verify that the apparent loss of sensing is not due to blanking periods.
- Verify that the event not being sensed is not occurring during the refractory period. If necessary, re-evaluate the refractory period.

  Note: An intrinsic event during the refractory period is not indicated by the **SENSE** LED.

- Perform sensing threshold test for the affected chamber. Provide at least a 2:1 safety margin.

  Note: If the patient does not have adequate intrinsic rhythm, consult a physician before the test.

- Increase the sensitivity for the appropriate chamber. Select **A Sensitivity** or **V Sensitivity**, then slowly turn the Menu Parameter dial clockwise (decrease mV until the ECG shows intrinsic activity).

  Note: Use caution when adjusting the sensitivity for patients with a history of sustained ventricular tachycardia.

9.1.3 Oversensing

Figure 53. Atrial oversensing

Figure 54. Ventricular oversensing

9.1.3.1 Keys to identifying oversensing

Verify the following when identifying if oversensing has occurred:

- ECG shows erratic prolonging or shortening of pacing interval.
- Persistent oversensing may result in asynchronous pacing or no pacing output.

9.1.3.2 Potential causes of oversensing

One (or more) of the following issues can cause oversensing:

Heart or patient related	Patient cable or lead related	Temporary pacemaker related
• T-wave sensing • Far-field sensing (sensing, P- waves, or R-waves) • Muscle sensing • EMI	• Insulation break • Conductor wire fracture	• Inappropriate sensitivity setting(s) • Cross-sensing (DDD or DDI pacing modes). ECG shows a paced A-V Interval of 110 ms or 70 ms occurring on a regular basis.

9.1.3.3 Potential solutions for oversensing

When troubleshooting oversensing, verify one or more of the following:

- Check the cable connections for loose wires.
- Replace the cable if there is an insulation break or wire fracture.
- Perform the sensing threshold test for the affected chamber. Provide at least a 2:1 safety margin.

  Note: If the patient does not have adequate intrinsic rhythm, consult a physician before the test.

- If the source is muscle activity, EMI, T-wave, or far-field sensing. Decrease the sensitivity for the affected chamber. Select **A Sensitivity** or **V Sensitivity**, and then slowly turn the Menu Parameter dial counterclockwise (increase mV value).

  Note: When adjusting sensitivity or output, verify the appropriate safety margin.

- If the source is cross sensing, try one or both of the following:
  - Decrease the ventricular sensitivity for the affected chamber. Select **V Sensitivity**, and then slowly turn the Menu Parameter dial counterclockwise (increase mV value).
  - Decrease the **A OUTPUT** by slowly turning the **A OUTPUT** dial counterclockwise.

9.1.4 Loss of capture

Figure 55. Loss of atrial capture

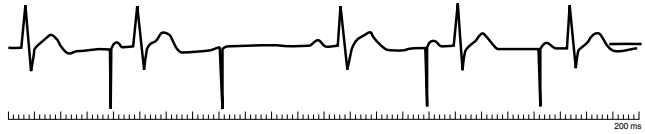
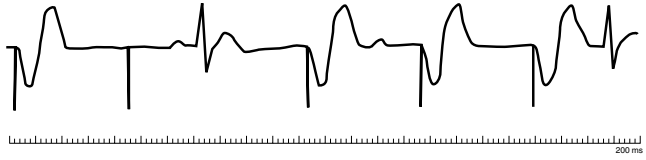


Figure 56. Loss of ventricular capture



9.1.4.1 Keys to identifying loss of capture

If the ECG shows no depolarization after delivery of a pacing stimulus, loss of capture has occurred.

Note: If the intrinsic event occurs just before pacing, see Section 9.1.2.

9.1.4.2 Potential causes of loss of capture

Heart or patient related	Patient cable or lead related	Temporary pacemaker related
• Increased stimulation threshold • Exit block • Tissue changes • General metabolic imbalances • Drug effects	• Loose connection at the connector block • Heartwire dislodgement • Inappropriate lead placement • Insulation break or wire fracture	• Inadequate output setting – mA • Inappropriate pacing mode selection

9.1.4.3 Possible misdiagnosis of loss of capture

Verify the following when determining if loss of capture has been misdiagnosed:

- Bipolar artifacts are too small to be seen.
- Digital ECG monitor or recorder is not sensitive to pacing spikes.

9.1.4.4 Possible solutions for loss of capture

When troubleshooting loss of capture, verify one or more of the following:

- Check the cable connections for loose wires.
- Replace the cable if there is an insulation break or wire fracture.
- Verify that the correct chamber is being paced.
- Verify the pacing mode.
- Perform the stimulation threshold test for the affected chamber. Provide at least a 2:1 safety margin.
- If necessary, increase the output for the appropriate chamber. Slowly turn the **A OUTPUT** or **V OUTPUT** dial clockwise until the ECG shows capture.

  Note: Use caution when adjusting the output for patients with a history of sustained ventricular tachycardia.

9.1.5 Stimulation of chest wall or diaphragm

9.1.5.1 Potential causes of stimulation of chest wall or diaphragm

Check the following when determining the causes of stimulation of chest wall or diaphragm:

Patient cable or lead related	Temporary pacemaker-related
• Improper lead placement • Loose connection at the connector block • Conductor wire fracture	• Excessive output settings – mA • Inappropriate pacing mode selection

9.1.5.2 Possible solutions for stimulation of chest wall or diaphragm

Verify the following when determining the causes of stimulation of the chest wall or diaphragm:

- Determine if the atrial or ventricular lead is the cause of the problem. First, reduce the output to one lead and then to the other lead. When the affected lead is identified, reduce the output for that lead.
- Perform the stimulation threshold test for the affected chamber. Set the output to a value more than 2 times the threshold value, but below the point of stimulating the chest or diaphragm.
- If the outcome does not improve, correct the placement of the leads.

9.1.6 No output pulse

9.1.6.1 Key to identifying no output pulse

The ECG does not show the pacing spikes when there is no output.

9.1.6.2 Possible misdiagnosis of no output pulse

The following can cause misdiagnosis of no output pulse:

- Pacing is inhibited because of sensed noise or intrinsic activity.
- Digital ECG monitor or recorder is not sensitive to pacing spikes.

9.1.6.3 Possible solutions for no output pulse

When troubleshooting no output pulse, do one or more of the following:

- Observe the pace indicators.
- Re-insert the patient cables.
- Replace the batteries.
- Change the ECG monitor or recorder.
- Re-select the pacing mode.
- Set output to the appropriate safety margin.

9.1.7 Hemodynamic changes

9.1.7.1 Keys to identifying hemodynamic changes

Check the following items when identifying possible causes of hemodynamic changes:

- Decreased blood pressure
- Altered brachial pulse rate

9.1.7.2 Possible solutions to hemodynamic changes

When troubleshooting hemodynamic changes, check one or more of the following:

- Check the pacing mode. If necessary, change to DDD pacing mode.
- Verify that sensing or capture has not been lost. Correct if necessary.
- Adjust the pacing rate (increase it in most cases).
- Adjust the **A-V Interval**.
- Consult a physician.

9.1.8 Pacemaker-mediated tachycardia

9.1.8.1 Keys to identifying pacemaker-mediated tachycardia

Check one or more of the following items when identifying pacemaker-mediated tachycardia:

- Occurs only in DDD pacing mode.
- Extended periods of ventricular pacing at or close to the **Upper Rate** setting.
- Patient may be symptomatic.
- The ECG shows retrograde P-waves after each paced ventricular event.

9.1.8.2 Potential causes of pacemaker-mediated tachycardia

One or more of the following items can cause pacemaker-mediated tachycardia:

- Retrograde conduction
- Loss of AV synchrony due to the effect of the **Upper Rate**
- PVC, sensed by the atrium, which re-triggers the **A-V Interval**
- PAC, blocked by the **Upper Rate**

9.1.8.3 Possible misdiagnosis of pacemaker-mediated tachycardia

Sinus tachycardia can cause a misdiagnosis of pacemaker-mediated tachycardia.

9.1.8.4 Possible solutions of pacemaker-mediated tachycardia

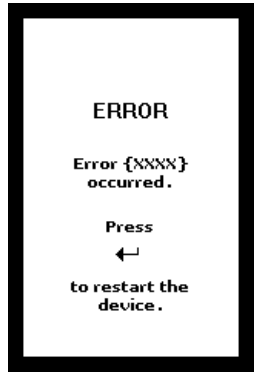
When troubleshooting pacemaker-mediated tachycardia, do one or more of the following:

- Consult a physician to determine the presence of sinus tachycardia.
- Restore the AV synchrony with one of the following adjustments:
  - Shorten the **A-V Interval**.
  - Increase the **PVARP**.
  - Adjust the **Upper Rate** in the presence of fast intrinsic atrial rates.
- Set the PVARP to a value longer than the retrograde conduction time. Use the ECG to determine the retrograde conduction time.
- Test sensing and stimulation thresholds.

9.1.9 Recoverable error message

If the temporary pacemaker displays the recoverable error message (see Figure 57) in the lower screen, press the Enter key. The temporary pacemaker restarts and performs the self-test.

Figure 57. Recoverable error message



9.1.10 Non-recoverable error message

If the temporary pacemaker displays the non-recoverable error message (see Figure 58) in the lower screen, contact Medtronic for service.

Figure 58. Non-recoverable error message

9.1.11 Button press detected error message

If the temporary pacemaker displays the Button Press Detected error message in the lower screen, a button has been pressed while the temporary pacemaker is turning on. Release any pressed key and the temporary pacemaker continues to power on normally.

Figure 59. Error – Button Press Detected

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